IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation, *et al*. Defendants.	)	Civil Action No. 04-12457 PBS

MEMORANDUM IN SUPPORT OF DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT AND IN OPPOSITION TO DEPUY MITEK'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT

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I. INTRODUCTION

Pursuant to the Court's January 31, 2007 Order, defendants Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together, "defendants") submit this summary memorandum explaining why, as the Court has construed the claim terms, defendants' motion for summary judgment of non-infringement should be granted and plaintiff DePuy Mitek, Inc.'s ("DePuy Mitek's") motion for summary judgment of infringement should be denied.[1] As the Court is aware, when the transitional phrase "consisting essentially of" is recited in a claim, an accused product avoids infringement if it contains an ingredient not recited in the claim and where that added ingredient materially affects the basic and novel characteristics of the invention. Defendants reassert here that since FiberWire contains a coating (*i.e.*, an unrecited ingredient) that materially affects the basic and novel characteristics of the '446 patent, it does not infringe the claims of the '446 patent.[2]

The relevant claim construction issue presented to the Court was what are the basic and novel characteristics of the '446 patent. In its January 31, 2007 Memorandum and Order, the Court defined the basic and novel characteristics of the '446 patent as follows:

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[1] In addition to this submission, defendants rely upon the entirety of the summary judgment record previously submitted in connection with the summary judgment motions, *Markman* submissions, and the motions to strike. The parties have discussed the scope of the instant memoranda and have agreed that the purpose is to explain each parties' position in light of the Court's interpretation and that it is not appropriate or necessary to expand the existing summary judgment record. Accordingly, the parties have agreed that no new evidence could be submitted in these memoranda beyond the evidence presented in the prior summary judgment, *Markman* and motions to strike submissions. The parties also exchanged drafts of the instant memoranda to better enable the parties to respond to each other's arguments.

[2] DePuy Mitek's original motion for summary judgment contended that the addition of nylon to Arthrex's TigerWire product does not materially affect the basic and novel characteristics of the '446 patent. Defendants responded that it does. Defendants have since agreed that the addition of nylon to TigerWire does not materially affect the basic and novel characteristics of the invention claimed in the '446 patent. Defendants, of course, continue to assert their other defenses in connection with TigerWire that they are asserting in connection with FiberWire.

> (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture.

Ex. 1 at 18-19.

It is undisputed that FiberWire suture contains a coating. It is also undisputed that coating materially improves the handleability, and especially knot tie-down performance of suture. Patent after patent -- most of them owned by DePuy Mitek's sister company, Ethicon, or DePuy Mitek's own expert in this case -- make this universally-known assertion. Every *DePuy Mitek and Ethicon* witness who testified on this subject -- *all six of them* -- likewise agreed. As a result, it comes as no surprise that Arthrex tells the world that coating is added to FiberWire to improve its handleability. Ex. 2. Even the '446 patent itself explains that coating is added to suture to improve handleability. In light of these undisputed facts, defendants are entitled to summary judgment that FiberWire does not infringe the claims of the '446 patent, and further, that DePuy Mitek's summary judgment motion for infringement should be denied.

II. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT THAT FIBERWIRE DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '446 PATENT

A. The Addition of Coating to FiberWire Avoids Infringement Because Coating Materially Affects the Basic and Novel Characteristics of the '446 Patent

It is undisputed that FiberWire includes a coating, and that coating is not a listed item in the asserted claims. Thus, the sole issue for this motion is whether coating materially affects the basic and novel characteristics of the '446 patent. *See, e.g.*, *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). The undisputed facts show that it does and accordingly, there is no infringement.

The first step is to define the basic and novel characteristics of the claims of the '446 patent. The Court's construction is: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture. Ex. 1 at 18-19. The Court's construction is virtually identical to defendants' proposed construction of "a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties." *See* Ex. 3 at 16.

Defendants submit that the couple of small wording changes do not change the construction from the one submitted by defendants. For example, while the Court uses the term "direct intertwining contact" in its claim construction, this term is synonymous with the term "braided," or "braided together," as proposed by defendants in their construction of the basic and novel characteristics. This was confirmed by DePuy Mitek's expert, Dr. Hermes, who when asked could not provide a single example of a braided construction that was not braided in direct intertwining contact. Ex. 4 at 212:25-213:5. Moreover, the Court itself treats the two terms as being synonymous. For example, to support its construction, the Court cites the specification as disclosing the "mechanical braiding" of the two dissimilar fibers (Ex. 1 at 17), and the "braided multifilaments" composed of dissimilar fiber-forming materials (Ex. 1 at 18), among other portions of the specification.

Although the wording of the Court's construction -- which concludes with the phrase "without significantly sacrificing the physical properties of the constituent elements of the suture" -- differs slightly from the wording of defendants' construction, there is no difference in substance. That the Court intended to adopt defendants' construction is reinforced by the fact

that the Court used this same exact language to describe defendants' contention regarding the construction of the basic and novel characteristics. Ex. 1 at 16. Whether one refers to *not* significantly sacrificing the physical properties of the *suture* or of the *constituent elements of the suture*, it does not make a difference. The two statements are synonymous.

Just as with defendants' proposed claim construction, in the Court's construction of the basic and novel characteristics, it is the handleability and pliability *of the suture* that is improved by braiding together two dissimilar yarns. For example, in supporting its claim construction, the Court noted "of significance, the specification states: in view of the deficiencies of the prior art, it would be desirable to prepare *multifilament sutures exhibiting* improved pliability and handling properties." Ex. 1 at 17-18 [italicized emphasis added, underlined emphasis in original.]

Once the basic and novel characteristics of the invention have been defined, the next step is to determine whether coating materially affects those basic and novel characteristics. An effect on the basic and novel characteristics of the claimed invention is "material" if the effect is of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). As we show below, the undisputed facts are that coating's affect on suture handleability, and especially knot tie-down, are of importance or of consequence to those of ordinary skill in the art.

As an initial matter, as the Court noted, a finding that an added ingredient materially affects the basic and novel characteristics of a patent can be made, as a matter of law, where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect. Ex. 1 at 14 (citing *AK Steel*). On this basis alone, defendants are entitled to summary judgment. The '446 patent first explains that multifilament braided sutures have a need for improved handleability. Ex. 5 at col. 1, ll. 12-28. The first prior

art solution to the handleability issue was to add coating. Ex. 5 at col. 1, ll. 29-31. The '446 patent, however, criticizes the use of coatings; explaining that coating adds costs and the possibility of braid stiffening. Ex. 5 at col. 6, ll. 15-17. The '446 patent specification goes on to explain that the use of coatings (and other methods) overlooked the importance of fiber-to-fiber mobility, and that by using the '446 patent invention, the handleability problems inherent in multifilament sutures can be solved *without the need* for coating. Ex. 5 at col. 6, ll. 13-17.[3] Thus, while the '446 patent states that coating can be added, the very same passage teaches that it is best to "avoid[]" and "eliminate[]" the use of coatings. Ex. 5 at col. 6, ll. 13-17. Accordingly, by merely reviewing the '446 patent disclosure, the Court should conclude, as a matter of law, that the addition of coating materially affects the basic and novel characteristics and that defendants are entitled to summary judgment. *See AK Steel,* 344 F.3d at 1240.

Should the Court feel it necessary to look beyond the teachings of the '446 patent, the additional evidence in the case overwhelmingly and undisputedly shows that the reason why multifilament sutures are coated is to improve the handleability aspects of the suture, particularly the knot tie down characteristics.[4] One need only look at the *uniform and overwhelming* evidence from DePuy Mitek itself, and from Ethicon, DePuy Mitek's sister company and the leading suture manufacturer in the world, to understand that this fact is so well-known in the suture art that it hardly bears citation.

(1) Ethicon patent after Ethicon patent, including patents of Alistair Hunter, one of the inventors of the '446 patent, explain the importance of coating multifilament sutures. *See*

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[3] Inventor Steckel made the same point during development; specifically noting that the braid had "superior handling properties," as compared with silk and Ethibond sutures and that the braid also "ranked better than silk and Ethibond in knot tie-down even without a coating." Ex. 6 at DMI 2666.

[4] As Ethicon's own Wound Closure Manual explains, knot tie down is the ease by which a knot slides down the suture. Ex. 7.

Ex. 8 at col. 1, ll. 14-18 ("a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture"); Ex. 9 at col. 1, ll. 11-15 (same); Ex. 10 at col. 1, ll. 12-15 ("multifilament suture [*sic*] typically require a surface coating to improve the pliability and knotting characteristics of the suture").

(2) A patent of Dr. Matthew Hermes, one of DePuy Mitek's experts in this case, makes the same assertion. Ex. 11 at col. 1. ll. 19-25 ("It has therefore become a common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well").

(3) Ethicon's Wound Manual makes the same point. Ex. 7 at 11 ("Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics.").

(4) Every DePuy Mitek and Ethicon witness who testified on the subject of why sutures are coated agreed. Whether testifying about the development of the suture for the '446 patent, Ethicon's and DePuy Mitek's development of Orthocord, or testifying about what is known to be important to those involved in suture, the testimony was exactly the same:

(a) Dr. Mark Steckel, a named inventor on the '446 patent, testified as follows:

> Q: [The '446 patent] says, "For example, multifilament sutures almost universally possess a surface coating to improve handling properties." Do you see that?
> A: Yes.
> Q: What's your understanding of what handling properties are being referred to in that sentence?
> A: My understanding, because the surface coating would be for knot handling, knot tie-down handling properties.
> Q: How about how well the knot slides, is that one of the things that --
> A: Oh yeah, that's part of knot tie-down.
> Q: Why don't you explain to me what is part of knot tie-down.

A: Okay. Yeah. I mean knot tie-down refers to the properties of a suture during the tying process, which would include the force, smoothness, roughness when one arm of the suture is being pulled against the second arm of the suture.

Ex. 12 at 295:23-296:21.

(b) Dennis Jamiolkowski, one of the originally-listed inventors of the '446 patent, and plaintiff's Rule 30(b)(6) witness, testified as follows:

A: Because sutures are frequently coated. In particular, braids are very often coated.
Q: Why is that?
A: Because a braid surface is not very smooth, generally, and consequently, tends to chatter much more than would a monofilament upon knot tie-down. So what the industry has done is that these suture materials that are multifilament in nature, that is, braids, would generally be coated. Not always, but generally.

Ex. 13 at 167:1-13.

(c) Shelby Cook Cornbluth, Project Leader on development of Orthocord suture, and also a Rule 30(b)(6) witness for plaintiff, testified as follows:

Q: Why is there coating on [Orthocord]?
A: To help with knot sliding.
Q: What do you mean when you say "To help with knot sliding"?
A: To help the knot slide down into the joint so that it cinches tightly. It – you want the knot to travel down the suture.
Q: Okay.
A: And it helps with that traveling down the suture.

Ex. 14 at 64:12-24.

(d) Gary McAllister, DePuy Mitek's Director of R&D for Orthocord suture, testified as follows:

Q: Why is there a coating on [Orthocord]?
A: It makes the handling much better, is my understanding that that's why coatings are put on there. It'll tie better. It'll slide better. They call it the hand. It improves the hand of the suture.

Ex. 15 at 48:21-49:2

(e) Ilya Koyfman, Ethicon's technical leader in charge of developing Orthocord suture, testified as follows:

> Q: I want to ask you a little bit about the -- what comes under the heading "braiding through coating" et cetera. Particularly, the last paragraph on the page. The sentence that says, "Coating selection depends on maintaining a fine balance between suture tie-down and knot security.
> A: Um-hm.
> Q: What did you mean by that sentence?
> A: The prime reason for applying coating is to have a good tie-down, good tie-down and tissue passage and so forth. When you apply coating you might affect other properties. So that's what I meant, you have to have a balance.

Ex. 16 at 63:10-23.[5]

(5) Ethicon and DePuy Mitek documents clearly demonstrate Ethicon's and DePuy Mitek's understanding that coating affects handleability when developing their Orthocord product (which competes directly with FiberWire) and other suture products. *See, e.g.*, Ex. 18 (Orthocord is coated "for improved slide ability and enhanced knot tying characteristics (*e.g.* knot slide)"); Ex. 19 ("The purpose of coating the Panacryl suture is to provide the suture with handling properties.").

(6) Articles in the field concur. *See* Ex. 20 at 525 ("synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics.").

In light of this overwhelming evidence, it comes as no surprise that Arthrex's documents, in a mirror image of DePuy Mitek's and Ethicon's documents and testimony, confirm that coating is added to improve handling characteristics. *See* Ex. 2 ("The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue"). And if

[5] Incredibly, Dr. Brookstein, DePuy Mitek's so-called suture expert, was the only witness who did not readily agree about the improving affect coating has on the handleability of multifilament suture. When confronted with this overwhelming evidence, Dr. Brookstein's meek response was that had not reviewed the material (although he had had the opportunity to do so) and that he simply does not know if this is the known purpose of adding a coating. Ex. 17 at 166:14-169:11. The only conclusion that can be drawn from his testimony is either that Dr. Brookstein is not an expert on suture coating (a likely conclusion because he testified that he only worked on one suture project in his professional life and he did not remember if it involved issues of coating (Ex. 17 at 165:8-166:3)) or Dr. Brookstein simply cannot be believed.

there were any doubt -- and there is absolutely none -- the '446 patent itself confirms that coating is added to improve handling characteristics of the suture, including knot tie-down *See* Ex. 5 at col. 1, ll. 29-31 ("multifilament sutures almost universally possess a surface coating to improve handling properties."); col. 6, ll. 5-8 ("If desired, the surface of the heterogeneous multifilament braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid.").

The evidence is overwhelming and cannot be disputed that the effect coating has on improving the handleability, including knot tie-down, of multifilament sutures is material, that is, important or of consequence to those of skill in the art. Since the undisputed facts are that coating is added to FiberWire, and it is universally known that coating materially affects what have been defined as the basic and novel characteristics of the '446 patent, summary judgment of no infringement should be granted.

B. DePuy Mitek offers no evidence to create a genuine issue of material fact regarding the effect of coating

DePuy Mitek has never disputed defendants' overwhelming evidence that coating materially affects handleability features of sutures in any of its prior filings. DePuy Mitek's inability to question these unassailable facts should be the dispositive answer to this issue. Unable to dispute the indisputable, DePuy Mitek tried to change the question and essentially took the position that FiberWire, somehow, is the only suture ever created where coating does not affect handleability characteristics.[6] It never had any evidence to support such a notion,[7] and

[6] DePuy Mitek has also asserted that defendants did not produce evidence that coating affects FiberWire's handling properties. But defendants did produce evidence that the coating on FiberWire improves the handleability characteristics of "knot sliding, knot tying and ease of passing suture through tissue." *See* Ex. 2.

DePuy Mitek has also asserted that the universal evidence of the affect of coating presented by defendants (which does not distinguish between types of coating) did not specifically state that those effects apply to silicone coating, such as used on FiberWire. *See* DePuy Mitek's Opposition to Arthrex's Motion for Summary Judgment (Paper No. 60) ("DePuy Mitek Opp.") at 17-18. DePuy Mitek, however, offers no evidence that the effects are different

in fact, DePuy Mitek appears to now be back-peddling from that untenable assertion. DePuy Mitek now readily admits (in its draft sent to defendants) that the silicone coating on FiberWire *does* have the same affects on FiberWire's handleability as are well-understood in the suture art.[8] But even if DePuy Mitek had not changed its position, none of its arguments creates a material factual dispute.

1. Dr. Brookstein does not create a genuine issue of material fact regarding the effect of coating

DePuy Mitek has attempted to create a genuine issue of material fact by relying on the testimony of Dr. Brookstein. Even if Dr. Brookstein were qualified to testify on the subject of suture coating -- he worked on only one suture project in his professional life and he could not remember if it involved issues of coating, and he was unable to confirm or deny the universal teachings about the effects of coating shown in the numerous patents and publications placed before him (*supra* at n.5) -- he never refutes *any* of the evidence presented by defendants regarding coatings well-known effects on suture handleability, and the little he does say does not create a disputed issue of fact.

In trying to explain why there is infringement under defendants' -- and thus, now the Court's -- assertion of the basic and novel characteristics of the '446 patent, Dr. Brookstein contended that FiberWire's two different yarns -- UHMWPE and PET -- contribute different properties to the braided suture and that the contribution of different properties is present both

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for silicone coating because there is none. In any event, to put the matter to rest, the undisputed evidence is that the handleability affects of coating are the same for silicone coating. Ex. 8 at col. 3, ll. 55-61; Ex. 9 at col. 3, ll. 55-61.

[7] The fact is that DePuy Mitek did not perform any tests of the effect that coating has on any suture characteristics, or at least any such tests that it produced to defendants. We do know, however, that DePuy Mitek did at least perform pliability tests on coated and uncoated FiberWire, but claimed privilege and steadfastly refused to produce the results. Ex. 21 at Tab 48.

[8] DePuy Mitek equates FiberWire's coating to the general "surface coating" described in the '446 patent -- the same coating that "further improve[s] the handleability and knot tie-down performance of the braid." Ex. 5 at col. 6, ll. 5-8.

before and after coating is added. Therefore, coating does not materially affect the basic and novel characteristics of the claimed invention. Ex. 22 at ¶¶ 23-24.

Stated another way, Dr. Brookstein asserts that coating does not affect the basic and novel characteristics of the claimed invention because "the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided." Ex. 22 at ¶ 27. When asked what this means, Dr. Brookstein replied that coating could only affect the basic and novel characteristics if "the coating in some *miraculous* way made those materials not yarns anymore" or "all of a sudden you had a set from A, a set from B and now it was some *magical structure* that wasn't yarns, it wasn't two sets, they were all the same, that would be a transformation." Ex. 17 at 399:1-400:15 [emphasis added.] Just to state the proposition shows its absurdity. In DePuy Mitek's and Dr. Brookstein's world, only "magic" and "miracles" can cause an added material to affect the basic and novel characteristics of an invention. That plainly is wrong.

DePuy Mitek has also attempted to rely on Dr. Brookstein's opinion "that the silicone was present in small amounts." DePuy Mitek Opp. at 17. Even if there were support for this conclusion, which there is not, it does not create a genuine issue of material fact since its purported relevance is to support Dr. Brookstein's opinion that "regardless of FiberWire's coating, FiberWire is still 'two dissimilar yarns braided together to achieve improved handleability or pliability without significantly sacrificing its physical properties.'" DePuy Mitek Opp. at 16-17. This is Dr. Brookstein's "magic" and "miracles" argument (Ex. 17 at 399:1-400:15), which has no basis in reality.

The undisputed evidence also shows that there is *no basis* for Dr. Brookstein's conclusion that the coating was present on FiberWire only in a "small amount," what Dr. Brookstein states to be 4.8% by weight coating. Ex. 22 at ¶ 27. All the *evidence* is to the

contrary. The patents in the field, including a patent of DePuy Mitek's other expert, Dr. Hermes, establishes that much less than the 4.8% coating measured by Dr. Brookstein is necessary to achieve the well-known suture handleability improvements.[9] Thus, the *undisputed evidence* is that Dr. Brookstein's 4.8% is a *large and more than sufficient amount* of coating to achieve handleability improvement. Unsupported conclusions, such as that submitted by the unqualified Dr. Brookstein, do not create a genuine issue of material fact to defeat a motion for summary judgment. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1080-81 (Fed. Cir. 2005).

2. DePuy Mitek cannot point to the '446 patent to create a genuine issue of material fact regarding the effect of coating

DePuy Mitek has also asserted that coating cannot affect the basic and novel characteristics of the claimed invention because the '446 patent says that "if desired, the surface of the . . . braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid." Ex. 22 at ¶ 33. Depuy Mitek is wrong for several reasons. The short answer is that the law is to the contrary. In *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239 (Fed Cir. 2001), just like here, the patent stated that certain materials could be added. *AFG*, 239 F.3d at 1242. Notwithstanding that disclosure, the Federal Circuit acknowledged that use of such materials (not identified in the claims) could materially affect the basic and novel characteristics of the invention. *AFG*, 239 F.3d at 1247. *See also*, *American Machine & Foundry Co. v. Liggett & Myers Tobacco Co.*, 172 F. Supp. 12, 19 (D. N.J. 1959) (although additional substances were disclosed in specification, they were not in claims and could materially affect basic and novel characteristics).[10] The issue is not whether the '446 patent says

[9] *See* Ex. 11 at col. 2, ll. 46-49 (disclosing about 0.01 to about 0.1 weight percent coating, and preferably about 0.02 to about 0.5 weight percent coating); Ex. 23 at col. 3, l. 62 – col. 4, l. 1 (shows coating compositions in the amount of up to 0.25% by weight).

[10] Even if DePuy Mitek's assertion had applicability in some circumstances, it would not apply here. The claims as originally filed with the Patent Office did *not* contain the "consisting essentially of" transitional phrase. Rather, the transitional phrase in the original claims was "comprising." For a "comprising" claim, it is no defense that the accused product has additional

one can add a coating; rather, the issue is whether the addition of coating materially affects the basic and novel characteristics. On that dispositive issue, the undisputed evidence is that the addition of coating does materially affect the basic and novel characteristics.

Moreover, an accurate reading of the passage to which DePuy Mitek points shows that it supports *defendants'* position, *not* DePuy Mitek's. The passage asserts that coating improves suture handleability and knot tiedown, itself an *admission* that coating materially affects the basic and novel characteristics. In fact, this same passage in the '446 patent specification goes on to say that "if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, *the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening*. Ex. 5 at col. 6, ll. 13-17, emphasis added. DePuy Mitek does not deny this because it can not. That the patent teaches it is best to "eliminate[]" and "avoid[]" coating amounts to a textbook disavowal of coatings.[11] The '446 patent does not create an issue of fact for DePuy Mitek. If anything, the disclosure of the '446 patent, without consideration of any other evidence, means that *defendants* are entitled to summary judgment as a matter of law. *See supra* at 5.

3. DePuy Mitek cannot point to Dr. Burks's testimony to create a genuine issue of material fact regarding the effect of coating

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unlisted materials. *Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). Accordingly, it makes perfect sense, as the application was originally filed, that the patent would state that coating could be used to further improve handleability. But once the transitional phrase "consisting essentially of" was added to the claim, which in turn narrowed the claim as a matter of law, DePuy Mitek's rationale falls apart. Since the transitional phrase was amended to "consisting essentially of," the use of a coating -- which is unlisted in the claims -- does avoid infringement if that coating materially affects the basic and novel characteristics of the invention. As described above, there is no question that it does.

[11] While tacitly admitting that the '446 patent does criticize coatings, DePuy Mitek tried to argue the patent does not criticize the type of coating used on FiberWire. But, contrary to DePuy Mitek's assertion, the '446 patent *does* criticize "thermoset" coatings (Ex. 5 at col. 1, ll. 52-54), the precise type of coating used on FiberWire. Ex. 24 at 95:5-7.

In another desperate attempt to create an issue of fact, DePuy Mitek tries to use the testimony of Dr. Burks, one of *defendants'* experts. Dr. Burks performed subjective opinion tests based upon handling some examples of coated and uncoated FiberWire. According to DePuy Mitek, Dr. Burks's tests create an issue of fact because he allegedly testified that, in some circumstances, the differences between the coated and uncoated FiberWire were "subtle." DePuy Mitek Opp. at 15-16.

As an initial matter, DePuy Mitek should be precluded from using Dr. Burks's testimony. Out of one side of its mouth, DePuy Mitek argued that Dr. Burks's testimony creates a fact dispute; yet out of the other side of its mouth, DePuy Mitek asserts, in its draft memorandum to defendants, that Dr. Burks's analysis is unreliable, doubts the genuineness of the samples he analyzed and accuses Dr. Burks of spoliation of evidence. Simply put, DePuy Mitek cannot try to create a disputed issue of fact with evidence it asserts it not competent.

In any event, DePuy Mitek is wrong on several counts. First, Dr. Burks's tests and his testimony has absolutely nothing to do with the mountain of evidence, undisputed by DePuy Mitek, that conclusively demonstrates that coating materially affects the basic and novel characteristics of the '446 patent.

Second, DePuy Mitek ignores the fact that Dr. Burks *correctly identified* which FiberWire sutures were coated and which were uncoated in *six different blind tests.* Dr. Burks conducted a tactile feel and knot tie-down test in connection with his expert report. He was not told which suture samples were coated and which were uncoated, but he identified *all three* samples correctly *every time* based *only* on his tactile feel and knot tie-down analysis. Ex. 25 at ¶¶ 9-13. Moreover, at his deposition, Dr. Burks was asked to conduct a blind test on three different suture samples. Here again, he was not told which samples were coated and which

were uncoated; and once again Dr. Burks got it right *every time* based only on his tactile feel and knot tie-down analysis. Ex. 26 at 96:6-14, 20-23.

Third, DePuy Mitek completely misconstrues the context in which Dr. Burks used the word "subtle." For example, DePuy Mitek ignores the fact Dr. Burks also stated at his deposition "I feel like there's a difference," and also that he was able to feel that the coated sutures were "generally smoother" than the uncoated sutures. Ex. 26 at 98:15-21; 87:10-13. The fact is that, read in the proper context, Dr. Burks merely testified to the obvious; if he did *a hundred* tests, he might not get it correct *every time.* Ex. 26 at 97:19-25.

DePuy Mitek also ignores the fact that when Dr. Burks used the word "subtle," he was referring to a tactile feel analysis conducted on dry suture, which is *not* how Dr. Burks generally uses FiberWire suture in his practice. The fact is that when Dr. Burks uses FiberWire suture in his practice, he uses it in a wet, surgical environment. As Dr. Burks stated in his report, "the difference between the two samples was even more pronounced when they were wet which is how I am accustomed to using FiberWire." Ex. 25 at ¶¶ 11,12.[12]

DePuy Mitek also asserts that Dr. Burks *may* not have been able to determine any difference if he had kept his gloves on. But Dr. Burks *never* testified that gloves *would* have made a difference. Notably, DePuy Mitek did *not* bring gloves to Dr. Burks's deposition for him to conduct his analysis. When asked if gloves would have made a difference to his analysis at his deposition -- in which he got *all three* right -- he responded that "I didn't do it that way so I guess I can't answer that and say yes or no." Ex. 26 at 72:16-20. Putting the testimony in the

[12] DePuy Mitek asserts that Dr. Burks characterized coated and uncoated FiberWire sutures as "pretty close" for both wet and dry testing. But that is not the case. The questioning to which DePuy Mitek refers only concerns the sentence in Dr. Burks's report that "during the analysis, I noticed that the samples labeled 'suture A' generally felt smoother than 'suture B.'" Ex. 26 at 87:7-88:3. DePuy Mitek never asked about Dr. Burks's reported findings that the difference between the coated and uncoated FiberWire "was even more pronounced when they were wet." Ex. 25 at ¶¶ 11-12. Thus, this testimony is unrebutted.

best light for DePuy Mitek, Dr. Burks did nothing more than *speculate* about the effect of gloves. Mere speculation cannot defeat a motion for summary judgment. *Invitrogen Corp.*, 429 F.3d at 1079.

Finally, even if DePuy Mitek's description of Dr. Burks' testimony had some validity, it is far from sufficient to create an issue of fact to defeat summary judgment. The Supreme Court held that "[t]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Nor will the existence of a mere scintilla of evidence suffice. *Id*. at 251. A genuine dispute requires evidence "such that a reasonable jury could return a verdict for the non-moving party." *Id*. at 248. "Evidence that is 'merely colorable' or is 'not significantly probative' will not prevent summary judgment." *Invitrogen Corp.*, 429 F.3d at 1076.

Here, DePuy Mitek does not even come close to presenting any evidence that would prevent summary judgment. The most that can be said about DePuy Mitek's evidence -- even assuming everything DePuy Mitek asserts about Dr. Burks is correct -- is that it fails to raise more than *a sliver of doubt* regarding whether coating materially affects the basic and novel characteristics of the invention. After all, he got the result correct *every time*. Particularly in view of *all* of the unrebutted evidence regarding the universally-known effects of coating, it is unrealistic to believe that a reasonable jury would look at DePuy Mitek's evidence regarding Dr. Burks and reach a verdict of infringement. Thus, DePuy Mitek's Dr. Burks "evidence" is legally insufficient to defeat summary judgment.

4. DePuy Mitek's new argument regarding coating's affect on FiberWire is not supported by any evidence, and thus, does not create a genuine issue of material fact

Finally, in a last ditch attempt to create the impression of a factual dispute, DePuy Mitek now makes what appears to be a new argument that FiberWire's coating has a minimal affect on its handleability. Curiously, DePuy Mitek points to Arthrex's development of FiberWire and asserts that the benefits obtained by braiding together the two different materials (*i.e.*, UHMWPE and PET) are so great that any benefit achieved by coating are minimal in comparison. But DePuy Mitek points to *nothing* in the FiberWire development work which even remotely concerned the effect of coating on FiberWire.

DePuy Mitek also cites to Dr. Brookstein (in its draft sent to defendants) as allegedly explaining that because it is just a lubricant, FiberWire's surface coating has a minimal effect relative to the dramatically improved handleability properties attributable to the heterogeneous braid of the invention compared to homogeneous sutures. Dr. Brookstein, however, never stated any of this; he never did any comparison of the impact of the coated and uncoated versions of FiberWire -- work that would have been necessary to support that alleged opinion. Rather, the portion of Dr. Brookstein's declaration upon which DePuy Mitek relies (Ex. 27 at ¶ 47) is merely a regurgitation of Dr. Brookstein's "opinion" that only a small amount of coating was added to FiberWire, which, as shown above, has no evidentiary support. *See supra a*t 11-12.

III. DEPUY MITEK IS NOT ENTITLED TO SUMMARY JUDGMENT ON THE ISSUE OF INFRINGEMENT

DePuy Mitek is already on record as stating its view that under defendants' proposed construction of the basic and novel characteristics of the '446 patent, it is not entitled to summary judgment on its own motion. Ex. 28 at 26:12-17; 27:4-11. Since, as described above, the Court has essentially adopted defendants' construction (*supra* at 3-4), DePuy Mitek, based on its own position in this case, is not entitled to summary judgment on its motion. DePuy Mitek's concession in its Opening Memorandum went even further, telling the Court that "if the Court does not adopt *its* construction of the term[] 'consisting essentially of,' there will . . . likely be

issues of fact that could preclude dispositive adjudication." Ex. 29 at n.2 [emphasis added]. The Court, of course, rejected DePuy Mitek's proposed interpretation; once again, DePuy Mitek has conceded that it is not entitled to summary judgment.

There is good reason for this concession. While defendants' submit that the overwhelming evidence described above about the effects of coating on multifilament sutures (*supra* at 5-9) entitled defendants to summary judgment, there can be no doubt that that evidence precludes DePuy Mitek from obtaining summary judgment on its own motion.[13]

A. DePuy Mitek's assertions regarding the '446 patent are contrary to the law and to the facts, and thus, DePuy Mitek's motion should be denied

Having no response to the mountain of evidence establishing the long-known material effect of coating on suture handleability, DePuy Mitek, now for the first time, cobbles together a summary judgment argument that it really doesn't matter that FiberWire is coated. According to

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[13] Defendants have also asserted that an adhesive is added to the ends of FiberWire which stiffens the suture. The addition of this "tipping material" is an infringement defense because it improves the suture's handleability by facilitating attachment to instruments. Ex. 30 at 53:23-54:2; Ex. 14 at 119:24-120:10; Ex. 16 at 106:5-10. DePuy Mitek's chief response is that tipping doesn't matter since most of the suture is not tipped, relying upon two Federal Circuit cases for support. But these cases do not apply here since they address a "comprising" transitional phrase and not a "consisting essentially of" transitional phrase, as in this case. For this additional reason, DePuy Mitek's motion should be denied.

Defendants have also asserted a reverse doctrine of equivalents defense, which contrary to DePuy Mitek's assertions, remains a viable defense. Defendants' expert, Dr. Mukherjee opined that "[t]he specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and pliability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the *precise opposite*. UHMWPE (the alleged first fiber-forming material) is added for strength and PET (the alleged second fiber-forming material) is added to improve knot tying -- a well-known handleability characteristic." Ex. 31 at 18.

DePuy Mitek's response is a contorted argument that FiberWire includes UHMWPE for improving handleability and that PET is added to FiberWire to improve its "knot holding strength." DePuy Mitek, however, has already admitted that UHMWPE is stiff (Ex. 27 at ¶ 25), which is the opposite of pliability. Moreover, the '446 patent never uses the term "knot holding strength." DePuy Mitek simply makes it up. The only strength disclosed in the '446 patent is tensile strength. Even if there were something to DePuy Mitek's argument, this is a classic fact dispute precluding summary judgment to DePuy Mitek.

DePuy Mitek, FiberWire's coating does not materially affect the basic and novel characteristics of the '446 patent because the patent teaches that the type of coating used on FiberWire can be added to suture.[14] DePuy Mitek's argument is wrong both on the facts and the law.[15]

DePuy Mitek is wrong for all the reasons explained above where we explained the disclosure in the '446 patent is not a defense to defendants' summary judgment motion. *See supra* at 12-13. As explained above, DePuy Mitek has the law wrong. An ingredient unlisted in the claim can materially affect the basis and novel characteristics of the invention even though the patent teaches that the ingredient can be added. *See AFG Indus., Inc.*, 239 F.3d at 1247; *see also American Machine*, 172 F. Supp. at 19.[16]

Likewise, as explained above (*supra* at 13), the passage in the '446 patent supports defendants' position, *not* DePuy Mitek's. The passage discloses that coating improves suture handleability and knot tie-down -- an *admission* that coating materially affects the basic and novel characteristics -- and the passage teaches that it is best to avoid and eliminate coating.

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[14] Also implicit in DePuy Mitek's argument is the legally-wrong assertion that the added ingredient must have a negative affect on the basic and novel characteristics in order to be material. This, of course, it not the law. *AFG Indus., Inc.*, 239 F.3d at 1246; *Bayer A.G. v. Sony Electronics, Inc.*, 228 F. Supp.2d 332, 346-47 (D. Del. 2002); *Binney & Smith v. Rose Art Indus., Inc.*, 1995 U.S. Dist. LEXIS 2602 at *30 (N.D. Ill. 1995); *American Machine*, 172 F.Supp. 12, 19 (D. N.J. 1959).

[15] DePuy Mitek asserts that: i) the type of coating criticized in the '446 patent is not the type of coating as on FiberWire; and ii) FiberWire's coating does not penetrate the braid. DePuy Mitek is wrong on both counts. The '446 patent criticizes "thermoset" coatings, the precise type of coating used on FiberWire. *Supra* at n.11. Moreover, the '446 patent criticizes the extra costs associated with all coatings. Ex. 5 at col. 6, ll. 15-16. On the second point, Dr. Mukherjee opined that based on Dr. Brookstein's micrographs, it appeared that coating did, in fact, extend into the braid. Ex. 31 at 30.

[16] DePuy Mitek misrepresented *Ex parte Boukidis*, 154 U.S.P.Q. 444 (B.P.A.I. 1966) as stating that if an unlisted ingredient is disclosed in the specification, it can not be excluded from a "consisting essentially of" claim. But, that is not what the court stated at all. Rather, the court merely observed that the claim term "'consisting essentially of' does *not necessarily limit* the claims to exclude other things when the specification clearly indicates that other constituents may be present as well." *Id*. at 444. [Emphasis added.] Of course, "other things" would not *necessarily* be excluded, since they would be excluded *only if* they materially affected the basic and novel characteristics of the invention.

There is nothing unique or unusual about this disclosure. It is entirely consistent with the mountain of evidence presented by defendants -- all of it undisputed -- and it is also entirely consistent with the undisputed fact that FiberWire *is* coated to improve its handleability, including knot-sliding, knot tying and ease of passing through tissue. Ex. 2.[17]

IV. CONCLUSION

For all the foregoing reasons, defendants' motion for summary judgment should be granted and DePuy Mitek's motion should be denied.

Dated: April 6, 2007

Respectfully submitted,

By: **/s/Charles W. Saber**

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[17] DePuy Mitek relies on two inapposite Federal Circuit cases -- *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349 (Fed. Cir. 2006) and *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004) -- to support its assertion that infringement of a "consisting essentially of" claim is not precluded where an unrecited structure in an accused product is unrelated to the claimed invention. First, DePuy Mitek's reliance on *Conoco* and *Norian* is misplaced because, even as DePuy Mitek admits, the transitional phrase at issue in those cases was *not* "consisting essentially of," rather it was "consisting of," which involves an entirely different legal analysis.

Even assuming DePuy Mitek is relying on *Conoco* and *Norian* to advance some sort of "argument-by-analogy," it is still to no avail. At best, *Conoco* and *Norian* stand for the unremarkable proposition that infringement is not avoided if the added ingredient is *unrelated to the claimed invention*. For example, in *Conoco* and *Norian*, the unrecited structures (*i.e.*, a certain impurity found in lubricants, and a mixing spatula present in a chemical kit, respectively) *were unrelated* to the claimed invention. The facts in this case are *very* different. Here, FiberWire's coating *is directly related* to the basic and novel characteristics of the invention. Even DePuy Mitek admits that FiberWire's coating improves its handleability and knot tie-down characteristics. Thus, any rationale DePuy Mitek may have for relying on *Conoco* and *Norian* quickly falls apart.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing MEMORANDUM IN SUPPORT OF DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT AND IN OPPOSITION TO DEPUY MITEK'S MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT was served, via the Court's email notification system on the following counsel for Plaintiff on the 6th day of April 2007:

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EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., Plaintiff,	)	
v.	)	CIVIL ACTION NO. 04-12457-PBS
ARTHREX, INC. and PEARSALLS LTD. Defendants.	)	

MEMORANDUM AND ORDER

January 31, 2007

Saris, U.S.D.J.

INTRODUCTION

Plaintiff DePuy Mitek, which specializes in the manufacture of surgical devices, alleges that Arthrex, Inc., and Pearsalls Ltd. (collectively "Arthrex"), two of Plaintiff's competitors, have infringed U.S. Patent No. 5,314,446 ("the '446 Patent"). Broadly, the '446 patent protects a braided surgical suture with two multi-filament yarns made from different materials. Beyond this definition, though, the parties disagree as to two key terms in the '446 Patent.

DePuy Mitek and Arthrex have moved for summary judgment on the issue of infringement. After a Markman hearing, the Court defines the two contested patent terms and **DENIES** without prejudice Plaintiff's motion for summary judgment of infringement and Defendants' motion for summary judgment of noninfringement.

FACTUAL BACKGROUND

1. The '446 Patent

The patent,[1] also known as the Hunter Patent, protects a sterilized heterogeneous braided suture. Claim One recites:

> A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
>
> a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
>
> b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
>
> c) optionally a core

'446 Patent col.8-9 ll.63-68, 1-9 (emphasis added). The construction of the underlined terms "consisting essentially of" and "PE" are disputed.

2. Procedural History

On November 19, 2004, DePuy Mitek filed this "suture suit" against Arthrex, claiming that two of Arthrex's products - FiberWire® and TigerWire® - infringe the '446 patent. It amended its complaint on September 9, 2005 to include similar allegations

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[1]On May 24, 1994, the United States Patent and Trademark Office issued the '446 Patent, which was assigned to to Ethicon, Inc., a New Jersey based medical device company wholly owned by Johnson & Johnson. On August 9, 2004, Ethicon transferred its interest in the '446 Patent to DePuy Mitek, another Johnson & Johnson subsidiary. DePuy Mitek currently owns this patent.

against Pearsalls, the company responsible for manufacturing the materials and braids that ultimately become part of the FiberWire and TigerWire sutures sold by Arthrex.

FiberWire is a surgical suture that is formed by braiding together yarns of ultra high molecular weight polyethylene ("UHMWPE") and yarns of polyethylene terephthalate ("PET"). These yarns are braided together so that they are in direct intertwining contact with one another. The Defendants also add a silicone coating to the braided suture, which, they argue, significantly improves the handleability and pliability of the device. TigerWire, unlike FiberWire, is composed of a UHMWPE filament and a yarn of nylon. In all other material aspects, however, TigerWire is identical to FiberWire.[2] As such, this Court will refer to these products collectively as "FiberWire."

The Defendants argue that they do not infringe the patent because the UHMWPE utilized in the FiberWire suture is different from the "general purpose" PE described in Claim One. Second, the Defendants submit that the coating on the FiberWire suture removes the product from the scope of Claim One of the '446 Patent.

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[2]As part of a motion to strike, the Defendants raise the possibility that TigerWire may be sufficiently dissimilar from FiberWire so as to warrant a separate examination of the two sutures. However, the differences between the two are not relevant to this opinion, although these distinctions may ultimately prove important.

DISCUSSION

1. Claim Construction

In construing a claim, this Court must first "look to the words of the claims themselves...to define the scope of the patented invention." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citation omitted). The language of the patent claims should be given first priority in the patent construction process because "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

Terms in the patent claims "are generally given their ordinary and customary meaning." Vitronics, 90 F.3d at 1582. The Federal Circuit has held that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313 (citations omitted). This "inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Id.

Despite the primary role that the plain meaning of the claim language plays in divining the subject matter of a patent, the

Federal Circuit has held that the plain language of the patents is best understood when viewed "in the context of the entire patent, including the specification." Id. Courts must examine the terms of the claim in light of the entire patent because

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention - the inventor's lexicography - must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Therefore, in interpreting a given claim term, the Court should first look to all intrinsic evidence. First, the Court consults the claims themselves, which "provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314 (quoting Vitronics, 90 F.3d at 1582). By examining "the context of the surrounding words of the [disputed] claim," an interpreter may properly comprehend and "determin[e] the ordinary and customary meaning of those [disputed] terms." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003).

Second, the Court must properly weigh the "specification

that concludes with the claims." Phillips, 415 F.3d at 1315. Therefore, the claims of a patent "must be read in view of the specification, of which they are a part." Id. (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995)). As a consequence, the Federal Circuit has opined: "The specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Thus, the specifications should guide this Court in its study of the evidence presented by the patent.

Finally, as part of this intrinsic evidence analysis, the Court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. "Like the specification," the Federal Circuit has suggested that "the prosecution history provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317. Nevertheless, the Court has cautioned that prosecution histories, unlike other forms of intrinsic evidence, "often lack[] the clarity of the specification and thus [are] less useful for claim construction purposes." Id. (citations omitted).

In contrast to the intrinsic evidence analysis endorsed by the Court in Phillips, extrinsic evidence, "consist[ing] of all evidence external to the patent and prosecution history,

including expert and inventor testimony, dictionaries, and learned treatises," is less favored in the claim construction analysis. Markman, 52 F.3d at 980 (citing Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1870)). Although the Court has expressly "authorized district courts to rely on extrinsic evidence," Phillips, 415 F.3d at 1317, the Federal Court warned that such exogenous evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Therefore, the Court has resolved to "emphasize[] the importance of intrinsic evidence in claim construction" because "extrinsic evidence...is unlikely to result in a reliable interpretation of patent claim scope." Phillips, 415 F.3d at 1319.

A. Meaning of "PE"

The parties dispute the proper scope of the term "PE" in the context of the '446 patent. Plaintiff contends that PE includes any polymer formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. By contrast, the Defendants argue that the term "PE" in the claims refers to general purpose PE, which excludes UHMWPE.

Plaintiff's expert, Dr. Matthew Hermes, provided the

scientific background, which is largely undisputed. PE is formed from repeating units of the monomer ethylene, (CH_2-CH_2). (Pl.'s Markman Br. Ex. 7 at ¶ 6.) PE may be referred to as (CH_2-CH_2)$_n$, where n equals a whole number and indicates the number of repeating monomeric units of ethylene in the polymer. The "molecular weight" of a PE chain is determined by the length of the chain (i.e., how high n is). UHMWPE is composed of the same monomer unit as any other polyethylene chain, but has a longer chain of the repeating ethylene monomer than "low molecular weight" or "medium molecular weight" PE. (Id. at ¶ 7.) In other words, the building block for a suture made from UHMWPE is a very long and heavy PE chain.

Claim One recites that the first yarn is composed of a fiber-forming material "from the group consisting of" seven specific polymers, including PE. The specification is clear that "PE" means polyethylene. '446 Patent col.4 l.27. This claim does not distinguish between kinds of PE possessing different molecular weights. The patentee did not limit the definition of PE. Cf. Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1373 (Fed. Cir. 2005) (determining that the claim term "saccharide" should not be construed only to include polysaccharides having ten or less monomer units because the claim, like the specifications, did not contemplate such a limited definition).

Plaintiff has also introduced evidence that a person having ordinary skill in the art would understand PE to mean all polymers made from PE. Dr. Hermes opines: "One of skill in the art would have known that 'PE' means 'polyethylene' and means all polymers made from ethylene. PE is the generic name for all types of PE, including ultra high molecular weight PE." (Pl.'s Markman Br. Ex 7 at ¶ 9.) To support Dr. Hermes's opinion, DePuy Mitek points to several technical dictionaries stating that the term PE encompasses all polymers consisting of ethylene monomers, including UHMWPE. For instance, the Encyclopedia of Polymer Science and Engineering states that "polyethylene [is] the 'common (source-based)' name for all polymers made from ethylene." (Pl.'s Markman Br. Ex. 7, Tab B).

The Defendants, however, argue that UHMWPE is a rigid and inflexible synthetic compound that would never enhance the pliability or lubricity of a suture.[3] As one of Arthrex's experts, Dr. Debi Prasad Mukherjee, argues:

> In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that,

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[3]Plaintiff has introduced evidence that UHMWPE is lubricious. (See Plaintiff's Ex. 9 at 51:15-55:5). The parties do not clearly explain the difference, if any, between a lubricious material and a stiff material in the context of a suture. Both appear to be related to handleability and pliability.

> generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known.

(Def.'s Markman Br. Ex. 12.) Although there is evidence that a person of ordinary skill in the art would understand that UHMWPE has different properties from other kinds of PE, Arthrex has introduced no evidence that one of ordinary skill would not understand the term PE to include UHMWPE.

Defendants argue that the prosecution history contains a disclaimer of the polymer UHMWPE, citing extensively to the discussion of the "Burgess reference" in the '446 Patent's history. (Def.'s Markman Br. Ex. 7-8.) The Burgess patent protects a type of braided fishing line that utilizes a high-tensile PE as part of its construction. In response to the rejection by the patent examiner of the suture claims based on the Burgess patent application, the applicant argued:

> One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement maybe the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact.

(DM1000196). (Emphasis in original). The applicant distinguishes Burgess: "In contrast, knot strength is not even mentioned in Burgess." (Id.) The applicant adds: "Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability....Although this thread has great strength

properties, it suffers from low elongation and, in turn, poor knot strength properties." (DM1000196). (Emphasis in original). The parties agree that "high-tensile polythene" is the European terminology for UHMWPE.

In overcoming the Burgess reference, the applicant does distinguish the suture from the fishing wire by drawing a distinction between materials used in the invention, pointing out the poor knot strength properties of high-tensile polythene. The Defendants argue that in distinguishing the heterogeneous braided suture from the fishing line composed of UHMWPE, the patentee limited the scope of its patent to ordinary general use PE. (Def.'s Markman Br. 12-13).

Plaintiff responds that the prosecution history is not a clear disclaimer of the UHMWPE. It emphasizes that the patent examiner and the applicant both routinely refer to the "high tensile polythene" described by the British Burgess patent as "polyethylene." (See, e.g., Pl.'s Markman Br. Ex. 3 at DMI000189.) By including "PE" in the list of polymers in the amended claim, Plaintiff contends, the inventors intended to include UHMWPE. Moreover, while the prosecution history does indicate that UHMWPE was not a preferred polymer because of its minimal stretchability, the applicant emphasized the distinction between the uses and purposes of the two devices:

> In view of the dissimilarities in property requirements between sutures and fishing line, there would be no

> incentive for a medical designer who wishes to improve the properties of a braided suture to study the art related to braided fishing lines. Even if he did use the teachings of fishing line art to modify a suture, then he would inevitably design an unacceptable suture.

(Pl.'s Markman Br. Ex. 3 at DMI000196-97.) In light of this language, Plaintiff's argument that there was never a clear disclaimer of UHMWPE is ultimately persuasive. See Andersen Corp. v. Fiber Composites, LLC, Nos. 05-1434, 06-1009, ____ F.3d ____, 2007 WL 188709, at *10 (Fed. Cir. Jan. 26, 2007) (citing Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1375 (Fed. Cir. 2005)) ("It is true that we have warned against importing limitations from the specification into the claims absent a clear disclaimer of claim scope.").

Pulling together all of these threads, this Court finds that an ordinary person skilled in the art of science and suture manufacturing looking to the plain language of the claim, the specification, and the prosecution history of the '446 Patent would conclude that "PE," as used in Claim 1, includes all polymers formed from a repeating ethylene monomer, including UHMWPE.

B. Meaning of "Consisting Essentially Of"

The second term disputed by the parties is the transitional phrase "consisting essentially of." Generally, three transitional terms are used in patent claims: (1) "comprising," which is an open term of transition (2) "consisting of," which is

a closed term of transition, and (3) "consisting essentially of," which is a partially open term perched between the extremes of the other two phrases. "In view of the ambiguous nature of the phrase," the Federal Circuit has opined that "consisting essentially of" "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (quoting PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

To determine those "basic and novel properties of the invention," the Court must look at the specification to determine "the goal of the invention as well as what distinguishes it from prior art." AK Steel, 344 F.3d at 1239-40 (holding that a limiting statement in the specification that silicon should not exceed 0.5% was a disclaimer which had an impact upon the meaning of the phrase "consisting essentially of aluminum.") The Court must also look at the prosecution history of a patent to determine whether an unlisted ingredient was excluded from the scope of a "consisting essentially of' claim. PPG, 156 F.3d at 1355.

Construing the "consisting essentially of" language in a patent claim can "at times blur the distinction between the separate steps in an infringement analysis." AK Steel, 344 F.3d

at 1240. Where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect, the issue may be resolved as a question of law. Id. In some situations, however, whether an additional ingredient materially affects the basic and novel characteristics of a patented invention is a question of fact for a jury. See PPG, 156 F.3d at 1357 (stating that it is the province of the jury to determine whether the iron sulfide had a material affect on the basic and novel characteristics of the patented glass).

The key question of claim construction for this term in Claim One involves discerning the basic and novel properties of the heterogeneous suture. Once this determination has been made, the Court can attempt to resolve the parties' disagreement over whether the surgical coating placed on FiberWire braided suture "materially affects" the basic and novel properties of the suture described by the '446 Patent. AK Steel, 344 F.3d at 1239.

The Defendants submit that this Court should construe the claim term "consisting essentially of" as follows:

> i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.
>
> ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

(Def.'s Markman Br. 16.) By contrast DePuy Mitek suggests:

> The 'novel and basic characteristics' of the invention are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *Consisting essentially of* excludes sutures that contain bioabsorbable materials as the first and second fiber-forming materials.

(emphasis in original) (Pl.'s Markman Br. 8.)

DePuy Mitek's primary argument is that the transitional phrase was inserted to exclude certain bioabsorbable materials in the prior art from the patent claims. The prosecution history demonstrates the "consisting essentially of" language was added by amendment. In the prosecution history, the examiner originally had rejected the claims based on two references - Doddi and Kaplan - which included braids of dissimilar materials. Plaintiff argues it amended the claims to exclude bioabsorbable materials from the first and second fiber-forming materials in order to further distance itself from this prior art.

In response to the examiner's rejection for anticipation by Kaplan, the applicant stated that in Kaplan, the "sheath yarn" was a "biocompatible yarn that is bioabsorbable or semi-bioabsorbable...In one embodiment the sheath yarn could also contain a non bio-absorbable yarn of one or more chemical compositions....Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn." (DMI 1000259). (Emphasis

added). Later, the applicant again distinguishes the prior art: "Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e., PTFE) and a second set of nonabsorbable yarn (i.e., PET). (DM 1000260).[4] Id. Thus the Plaintiff argues there is a clear and express disclaimer of bioabsorbable yarns in the prosecution history. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005).

Defendants contend that the prosecution history does not support this interpretation because the patent specification provides, "The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired." '446 Patent col.3 ll.63-65 (emphasis added). Still, under the doctrine of prosecution disclaimer, Plaintiff's argument that it clearly disclaimed bioabsorbable yarns to overcome the rejection seems persuasive. Nonetheless, this debate seems largely beside the point because the issue here involves coatings, not bioabsorbable yarns.

The Defendants contend that the invention's primary basic and novel characteristic is that it improves the handleability and pliability of a suture without significantly sacrificing any physical properties of the constituent materials of the device, like strength or knot tiedown. The specifications reveal that

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[4]In addition, the plaintiff pointed out that Kaplan taught that sheath yarns listed in the invention should not be used in sheaths.

the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention" section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 ll.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 ll.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 ll. 6-8. These "[b]raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 ll.8-10. The specification points out, "Unfortunately, the prior art abounds with attempts to improve specific properties of multi-filament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multi-filament sutures almost universally possess a surface coating to improve handling properties." Id. at col. 1 ll. 26-31. It continues: "All of the attempts described in the prior art have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability." Id. at col. 2 ll. 14-17. Of significance, the specification states:

> In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties."

Id. at col.2 ll, 32-37 (Emphasis added).

Plaintiff argues that increased pliability is a property only of the preferred embodiment, pointing to the passage that states: "For example, in preferred embodiments, the heterogenous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security." Id. at col. 2 ll. 50-67. As shown above, this is a myopic view of the specification, which states throughout that a primary goal of the invention is to achieve enhanced pliability and handleability. The sterilized heterogeneous braids described in this patent seek to achieve a high degree of pliability and handleability by mechanically blending together two dissimilar synthetic yarns.

Therefore, this Court concludes that the basic and novel properties of the suture described in the '446 Patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability

without significantly sacrificing the physical properties of the constituent elements of the suture.

2. Summary Judgment

As noted previously, both DePuy Mitek and Arthrex have moved for summary judgment on the issue of patent infringement. However, the summary judgment record is a mess because of the multiple motions to strike, each with extensive appendices and confusing briefing. This Court has allowed Arthrex to supplement Dr. Gitis's expert report to correct certain typographical and computational errors. Moreover, DePuy Mitek has launched a Daubert challenge to Defendants' expert report, and it is difficult to figure out the various expert opinions on the affect of the coatings on the accused devices. Accordingly, this Court will deny these cross-motions for summary judgment without prejudice.

ORDER

Plaintiff's motion for summary judgment of infringement is **DENIED** without prejudice (Docket No. 36). Defendants' motion for summary judgment of noninfringement is **DENIED** without prejudice (Docket No. 39).

All parties are ordered to submit a single brief, not to exceed 20 pages, on the summary judgment issue of patent infringement within 60 days in light of the Court's construction of the '446 Patent. The parties shall file no additional motions

to strike, and there shall be no replies or sur-replies.

PATTI B. SARIS
United States District Judge

EXHIBIT 2

FiberWire™

IMPORTANT PRODUCT INFORMATION
WICHTIGE PRODUKTINFORMATION
NOTICE D'UTILISATION IMPORTANTE
IMPORTANTI INFORMAZIONI PER L'USO
INSTRUCCIONES IMPORTANTES PARA EL USO

CE 0086

Arthrex®

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Arthrex®

DFU-0065
Rev. 6

ENGLISH

Description:
Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (swaged) to the ends in a variety of sizes. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-dyed (white) or dyed and meets or exceeds U.S.P. and European standards (except for diameter).

Indications:
Arthrex FiberWire is indicated for use in soft tissue approximation and or ligation. FiberWire is not for use in cardiac indications.

Actions:
Arthrex FiberWire, when tested per ISO/DIS 10993, *Biological Evaluation of Medical Devices-Part 10: Tests for Irritations and Sensitization*, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength *in vivo*.

Contraindications:
None known

Warnings:
Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Arthrex FiberWire for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:
In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all knots have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

Do not grasp the needle at the point or swage, to avoid damage to these areas. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharps" containers.

Adverse Reactions:
Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:
Arthrex FiberWire suture is supplied sterile.
Method of sterilization - EO
Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

Storage Conditions:
Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:
The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with swaged needles. The Arthrex FiberWire is available in non-dyed (white) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING

- (2) Do not reuse
- QTY Quantity
- STERILE EO: Sterile unless the package is damaged or open. Method of sterilization - EO
- STERILE R: Sterile unless the package is damaged or open. Method of sterilization - gamma radiation
- LOT Lot number
- ⚠ See package insert
- CE The product meets the essential requirements of Medical Device Directive 93/42 EEC.
- ⧗ Use by - year & month

DEUTSCH

Beschreibung:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an den Fadenenden befestigten (gesenkgeschmiedeten) Nadeln unterschiedlicher Größen erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe. Arthrex FiberWire ist ungefärbt (weiß) oder gefärbt erhältlich und entspricht oder übertrifft USP- und europäische Standards (mit Ausnahme des Durchmessers).

Anwendungsgebiete:
Arthrex FiberWire ist für Weichgewebeapproximation und/oder -ligation vorgesehen. FiberWire nicht für Kardio-Indikationen verwenden.

Funktionen:
Tests bei Arthrex FiberWire gemäß ISO/DIS 10993, *Biological Evaluation of Medical Devices - Part 10: Reiz- und Sensibilisierungstests* ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nahtmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch unter Umständen vom umgebenden Bindegewebe eingekapselt. Bei Arthrex FiberWire wurde *in vivo* keine signifikante Änderung der Zerreißfestigkeit festgestellt.

Gegenanzeigen:
Unbekannt

Warnhinweise:
Nicht resterilisieren. Unbenutztes Fadenmaterial nach dem Öffnen entsorgen. Von Hitze fernhalten.

Benutzer sollten vor dem Verschließen von Wunden mit Arthrex FiberWire mit den chirurgischen Prozeduren und Techniken vertraut sein, bei denen nicht-absorbierbarer Faden verwendet wird, da das Dehiszenzrisiko je nach Anwendungsstelle und verwendetem Fadenmaterial unterschiedlich ist.

Wie bei Fremdkörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadenmaterials mit Salzlösungen, (wie sie z.B. im Harn- und Gallentrakt vorhanden sind) zu Calculusbildung führen. Bei der Drainage und beim Schließen von infizierten oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorsichtsmaßnahmen:
Bei der Handhabung dieses oder jedes anderen Fadenmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Schäden durch Zusammendrücken oder Abklemmen mit chirurgischen Instrumenten wie Zangen oder Nadelhaltern nach Möglichkeit vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbildungstechniken sicher befestigt wurden. Voraussetzung für angemessene Knotenhaltbarkeit ist die Verwendung von flachen, quadratischen Schleifen mit zusätzlichen Verknotungen, je nach chirurgischer Situation und Erfahrung des Chirurgen. Besonders beim Verknoten von monofilen Fäden sind unter Umständen zusätzliche Verknotungen angebracht. Sorgfältig vorgehen, um Schäden am umgebenden Gewebe und Benutzerpunktierung durch falsche Handhabung der Nadelspitze zu vermeiden.

Die Nadel nicht an der Spitze oder am Gesenk festhalten, um eine Beschädigung dieser Bereiche zu vermeiden. Nadeln können durch Umformen an Stärke verlieren und gegen Verbiegen und Abbrechen weniger widerstandsfähig werden. Nadeln in entsprechend gekennzeichneten Behältern entsorgen.

Nebenwirkungen:
Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Zu den bei nicht-absorbierbarem Faden üblichen Reaktionen zählen unter Umständen Dehiszenz, Calculusbildung in Harn- und Gallenwegen bei längerem Kontakt mit Salzlösungen (wie sie im Urin und in der Gallenflüssigkeit vorhanden sind), verstärkte Bakterieninfektion, minimale akute Gewebeentzündungen, Schmerzen, Ödeme und Erythema an der Wundstelle. Versehentliches Stechen mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Sterilisation:
Arthrex FiberWire wird steril geliefert.
Sterilisationsmethode - EO.
Nicht resterilisieren. Bei beschädigter oder zuvor geöffneter Packung nicht verwenden. Offenes, unbenutztes Fadenmaterial entsorgen.

Lagerungsbedingungen:
Unter 25 °C trocken und fern von direkter Hitzeeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Lieferform:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Das Fadenmaterial wird steril in vorgeschnittenen Längen und in manchen Fällen mit gesenkgeschmiedeten Nadeln geliefert. Arthrex FiberWire ist ungefärbt (weiß) und gefärbt erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE

- (2) Nicht wiederverwenden!
- QTY Quantität
- STERILE EO: Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - EO
- STERILE R: Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - Bestrahlung
- LOT Chargenbezeichnung
- ⚠ Siehe Packungsbeilage
- CE Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie des Rates über Medizinprodukte 93/42/EWG.
- ⧗ Verwendbar bis Jahr und Monat

FRANÇAIS

Description:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Arthrex FiberWire est également commercialisée avec des aiguilles serties de différentes tailles. Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou teintée, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Indications:
La suture Arthrex FiberWire est indiquée pour la ligature et le rapprochement des tissus mous. La suture Arthrex FiberWire n'est pas indiquée pour la chirurgie cardiaque.

Réactions:
Aucune réaction allergique ou sensible n'a été observée lors de la soumission de la suture Arthrex FiberWire au test exigé par la norme ISO/DIS 10993 / *Evaluation biologique des dispositifs médicaux, Partie 10 : Essais d'irritation et de sensibilisation.* La suture teintée et le traitement en surface de la suture sont pharmacologiquement inactifs.

La suture Arthrex FiberWire est non résorbable. Elle peut cependant être encapsulée par le tissu conjonctif. Selon les données disponibles, la résistance à la traction de la suture Arthrex FiberWire ne change pas de manière significative *in vivo*.

Contre-indications:
Aucune contre-indication connue.

Précautions d'emploi:
Ne pas stériliser à nouveau. Jeter toute suture non utilisée dont l'emballage a été ouvert. Ne pas exposer à la chaleur.

Tout praticien suturant une plaie avec la suture Arthrex FiberWire doit être familiarisé aux techniques chirurgicales recommandées pour les matériaux non résorbables, car le risque de déhiscence de la plaie varie selon le site de l'intervention et selon le type de suture employé.

Comme avec tout matériau exogène, un contact prolongé de cette suture ou de tout autre fil avec un fluide salin, comme ceux circulant dans les voies urinaires ou biliaires, peut conduire à la formation de calculs. Le praticien devra respecter les règles chirurgicales relatives au drainage et à la fermeture de plaies infectées ou contaminées.

Précautions d'emploi:
Comme avec toute autre suture, éviter d'abîmer le fil lors de sa manipulation. Ne pas écraser le fil avec des instruments chirurgicaux comme une pince ou un porte-aiguille.

Réaliser tous les nœuds conformément aux techniques chirurgicales en vigueur. Opter pour le nœud plat, qui garantit une bonne sécurité et qui est largement utilisé, avec boucles supplémentaires en fonction du cas chirurgical et de l'expérience du praticien. Si le fil est monofilament, prévoir des boucles supplémentaires pour les nœuds. Bien contrôler la pointe de l'aiguille pour éviter de piquer les tissus environnants ou de blesser le praticien.

Ne pas saisir l'aiguille par sa pointe ou par son attache sur le fil pour éviter de l'endommager. Eviter de modifier la courbure des aiguilles pour ne pas réduire leur résistance à la déformation et à la rupture. Après usage, jeter les aiguilles dans un récipient spécial pour objets pointus et tranchants.

Effets indésirables:
Aucun effet indésirable particulier n'a été observé lors des tests du fil Arthrex FiberWire chez l'animal. Comme avec les autres fils de suture non résorbables, les réactions suivantes sont possibles : déhiscence de la plaie, formation de calculs dans les voies urinaires ou biliaires si contact prolongé avec des fluides salins comme l'urine ou la bile, infectivité bactérienne accrue, inflammation tissulaire minime, douleur, œdème et érythème au niveau de la plaie. Toute blessure avec une aiguille chirurgicale contaminée peut transmettre des germes pathogènes présents dans le sang.

Stérilisation:
La suture Arthrex FiberWire est livrée stérile.
Méthode de stérilisation : oxyde d'éthylène
Ne pas stériliser à nouveau. Ne pas utiliser si l'emballage est ouvert ou endommagé. Jeter les sutures non utilisées si leur emballage est ouvert.

Conditions de stockage:
Conserver à une température maximale de 25°C et à l'abri de l'humidité comme des sources de chaleur directes. Ne pas utiliser après la date d'expiration.

Présentation:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différentes longueurs précoupées. Elle est aussi disponible avec des aiguilles serties. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou en couleurs (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus.

SYMBOLES UTILISÉS SUR L'ÉTIQUETAGE

Ne pas réutiliser — QTY Quantité
STERILE EO Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - EO
STERILE R Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - irradiation
LOT No. de lot — Consulter la notice accompagnant le produit
CE Ce produit est conforme aux exigences de la directive sur les dispositifs médicaux CEE 93/42.
À utiliser avant le (mois/année)

ITALIANO

Descrizione:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). FiberWire Arthrex può essere venduto anche con aghi di varie dimensioni attaccati (saldati) alle estremità. La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto. FiberWire Arthrex è disponibile sia non tinto (bianco) che tinto e soddisfa o supera gli standard U.S.P. ed europei (non per diametro).

Indicazioni:
FiberWire Arthrex è indicato per l'approssimazione e/o la legatura dei tessuti molli. FiberWire non va utilizzato in interventi cardiaci.

Azioni:
FiberWire Arthrex, quando testato per ISO/DIS 10993, *Valutazione biologica dei dispositivi medici-Parte 10: I test per irritazioni e sensibilizzazione,* non hanno evidenziato reazioni allergiche o ipersensibilità. La sutura e il rivestimento tinti sono farmacologicamente inattivi.

FiberWire Arthrex non viene assorbito, ma può essere incapsulato nei tessuti connettivi circostanti. Non sono noti per FiberWire Arthrex cambiamenti significativi nella resistenza alla tensione *in-vivo*.

Controindicazioni:
Nessuna nota

Avvertenze:
Non risterilizzare. Una volta aperte, gettare le suture non utilizzate. Non esporre al calore.

Gli utenti devono conoscere bene le procedure e le tecniche chirurgiche relative alle suture non assorbibili prima di utilizzare FiberWire Arthrex per la chiusura delle ferite, in quanto il rischio di deiscenza della ferita può variare in base al sito di applicazione ed al materiale utilizzato per la sutura.

Come per qualsiasi corpo estraneo, il contatto prolungato di questa e qualsiasi altra sutura con soluzioni saline, come quelle presenti nel tratto urinario o biliare, può risultare nella formazione di calcoli. È necessario seguire una pratica chirurgica corretta per il drenaggio e la chiusura di ferite infette o contaminate.

Precauzioni:
Nel trattare questo o qualsiasi altro materiale per sutura, occorre fare attenzione ad evitare danni dovuti al maneggiamento. Evitare danni da schiacciamento o piegature dovuti all'applicazione di strumenti chirurgici, inclusi forcipi o porta-aghi.

Assicurarsi che tutti i nodi siano stati legati usando le tecniche chirurgiche di annodatura accettate. Una sicurezza adeguata del nodo richiede la tecnica chirurgica accettata di legature piatte e quadrate, nonché di ulteriori avvolgimenti in base al caso chirurgico e all'esperienza del chirurgo. L'uso di avvolgimenti aggiuntivi può essere particolarmente appropriato per l'annodamento di monofilamenti. Evitare di recare danni al tessuto circostante o alla puntura dovuti ad una manipolazione non corretta della punta dell'ago.

Non afferrare l'ago per la punta o dalla saldatura, onde evitare danni a queste aree. Il riadattamento degli aghi può indebolirli e renderli meno resistenti alle piegature ed alle rotture. Gettare gli aghi usati in contenitori per materiale «affilato».

Effetti indesiderati:
Non si sono riscontrati effetti indesiderati con l'uso del prodotto FiberWire Arthrex nei test sugli animali. Le reazioni comuni alle suture non assorbibili possono includere la deiscenza della ferita, la formazione di calcoli nei tratti urinario e biliare dovuta al contatto prolungato con soluzioni saline come urina e bile, infettività batterica elevata, minima reazione del tessuto alle infiammazioni acute, dolore, edema ed eritema al sito della ferita. Il contatto involontario dell'ago con aghi chirurgici contaminati può risultare nella trasmissione di patogeni veicolati dal sangue.

Sterilizzazione:
La sutura FiberWire Arthrex viene fornita sterile.
Metodo di sterilizzazione - EO
Non risterilizzare. Non utilizzare se la confezione è aperta o danneggiata. Gettare le suture aperte non utilizzate.

Condizioni di conservazione:
Conservare al di sotto di 25°C, lontano da umidità e calore diretto. Non utilizzare dopo la data di scadenza.

Come si presenta:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro. La sutura viene fornita sterile in lunghezze pretagliate ed in alcuni casi con aghi saldati. FiberWire Arthrex è disponibile tinto o non tinto (bianco). La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

SIMBOLI USATI SULL'ETICHETTA

Monouso — QTY Quantità
STERILE EO Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - EO
STERILE R Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - Raggi Gamma
LOT Numero di lotto — Fare riferimento all'inserto contenuto nella confezione
CE Il prodotto è conforme ai requisiti essenziali della Direttiva CEE 93/42 sui Dispositivi Medici.
Da usarsi entro anno e mese

ESPAÑOL

Descripción:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas de U.S.P. para suturas, excepto en el diámetro). También es posible encontrar la sutura FiberWire de Arthrex en diversos tamaños y con agujas incorporadas (enhebradas) en los extremos. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido. La sutura FiberWire de Arthrex viene en modelos sin teñir (blanca) o teñida y cumple o supera las normas de U.S.P. y Europa (excepto en el diámetro).

Indicaciones:
La sutura FiberWire de Arthrex está indicada para aplicaciones de aproximación y ligadura de tejido blando. La sutura FiberWire no está indicada para uso cardiaco.

Acciones:
Sutura FiberWire de Arthrex, sometida a prueba de acuerdo con la norma ISO/DIS 10993, *Evaluación Biológica de Dispositivos Médicos-Sección 10: En pruebas para detección de irritaciones y sensibilidad,* no hubo reacciones alérgicas ni de sensibilidad. La sutura teñida y el recubrimiento son inactivos farmacológicamente.

La sutura FiberWire de Arthrex no se absorbe, pero podría encapsularse en los tejidos conjuntivos adyacentes. La sutura FiberWire de Arthrex no presenta cambios significativos conocidos en cuanto a resistencia a la tracción *in vivo*.

Contraindicaciones:
Ninguna conocida

Advertencias:
No esterilizar de nuevo. Una vez abierto el paquete, desechar la sutura no utilizada. No exponer al calor.

Los usuarios deberán conocer los procedimientos quirúrgicos y las técnicas con suturas no absorbibles antes de utilizar FiberWire de Arthrex para cerrar heridas, ya que el riesgo de dehiscencia de las heridas varía según el sitio de aplicación y el material de sutura utilizado.

Al igual que ocurre con todo cuerpo extraño, el contacto prolongado de esta sutura, o de cualquier otro tipo de sutura, con soluciones salinas como las halladas en los tractos urinario o biliar, podría producir cálculos. Se deben usar métodos quirúrgicos aceptables en relación con el drenaje y cierre de heridas infectadas o contaminadas.

Precauciones:
Se debe tener cuidado al manipular este o cualquier otro material de sutura para evitar dañarlo. No utilice instrumentos quirúrgicos o de aplicación tales como fórceps o porta-agujas para evitar aplastar o plegar el material.

Cerciórese de que todos los nudos se hayan fijado por medio de técnicas aceptadas para nudos quirúrgicos. Para la fijación correcta de los nudos es necesario utilizar la técnica quirúrgica aceptada de nudos planos y cuadrados con lazadas adicionales, según lo requieran las condiciones quirúrgicas y la experiencia del cirujano. El uso de lazadas adicionales podría ser especialmente útil en la elaboración de nudos de monofilamentos. Debe tenerse cuidado para evitar daños al tejido adyacente o punciones producidas por el usuario al manipular incorrectamente la punta de la aguja.

No sujete la aguja por la punta ni por el ojo para evitar daños en esas partes. Si se modifica la forma de las agujas, éstas podrían perder su firmeza y ser menos resistentes a las curvaturas y el rompimiento. Deseche las agujas usadas en recipientes para objetos punzantes.

Reacciones adversas:
No se han detectado reacciones adversas del producto FiberWire de Arthrex en pruebas con animales. Entre las reacciones comunes de las suturas no absorbibles se encuentran: dehiscencia de las heridas, formación de cálculos en los tractos urinario y biliar en condiciones de contacto prolongado con soluciones salinas tales como la orina y la bilis, mayor propensión a infecciones bacterianas, reacción mínima inflamatoria aguda del tejido, dolor, edema y eritema en el sitio de la herida. El pinchazo accidental con agujas quirúrgicas usadas podría causar la transmisión de patógenos a través de la sangre.

Esterilización:
La sutura FiberWire de Arthrex se suministra estéril.
Método de esterilización - EO
No esterilizar de nuevo. No utilizar si el paquete llega abierto o dañado. Desechar las suturas abiertas que no se hayan utilizado.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25° C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en cortes de longitud predeterminada y en algunos casos con agujas enhebradas. La sutura FiberWire de Arthrex se encuentra disponible en modelos sin teñir (blanca) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

SIMBOLOS UTILIZADOS EN LAS ETIQUETAS

No reutilizar — QTY Cantidad
STERILE EO Estéril mientras el envase no sea abierto o dañado. Método de esterilización - EO
STERILE R Estéril mientras el envase no sea abierto o dañado. Método de esterilización - irradiación
LOT Número de lote — Ver folleto en el interior del paquete
CE Este producto cumple con las normas básicas de la Directiva de productos médicos, 93/42 CEE.
Caduca - año y mes

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S OPENING BRIEF ON CLAIM CONSTRUCTION

Dated: August 11, 2006

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Counsel for Defendants
Arthrex, Inc. and Pearsalls Ltd.

did not have enough knowledge to disagree with those authors. Ex. 15 at 246:25 – 247:19. This is the approach the *Phillips* court warned about.

As made clear by the entirety of the intrinsic evidence – *i.e.*, the specification and the prosecution history – when the inventors used the term "PE," they intended to mean general purpose polyethylene and not UHMWPE. Even DePuy Mitek's own expert, on his initial reading of the patent, recognized that the specification "seems to teach away from UHMWPE." For all the above reasons, Defendants' proposed construction should be adopted.

B. "Consisting essentially of"

Claim Term	Construction
Consisting essentially of	i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention. ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

As described above, it is well settled that the transitional phrase "consisting essentially of," as it appears in the asserted claims of the '446 patent, is construed to mean that infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp.*, 344 F.3d at 1239. The parties do not appear to dispute this basic principle. The parties do dispute, however, the identity of the "basic and novel characteristics of the claimed invention." As the Federal Circuit stated in *AK Steel*, one need look no further than the specification in order to make that determination. *Id.* at 1239. This case is no different.

Dated: August 11, 2006

Respectfully submitted,

By: /s/Salvatore P. Tamburo

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EXHIBIT 4

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

----------x

DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,

Defendants.

----------x

DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

invention during the time you were working at US Surgical?

MR. BONELLA: Object to the form.

THE WITNESS: I don't recall.

BY MR. SABER:

Q. Would this definition of braid or braided that you used in this patent result in yarns that are in direct intertwining contact as you understand that term from the '446 patent?

A. It's my opinion that the -- that the sheath yarns would be in direct intertwining contact.

Q. Now, in -- in your patent, this definition of braid or braided didn't require that there be a core, correct?

A. It did not require that there be a core, that is correct.

Q. And the -- on column three, line ten, it says the braided suture of this invention can optionally possess in addition to the braided structure itself a core component around which the braid is constructed?

A. Yes.

Q. Is that correct?

A. That's correct, that's what it reads.

Q. Do you agree that Figure 6 is an elongated member?

A. Yes, I do.

Q. And same thing about Figure 8?

A. Yes, I -- yes, sir.

Q. Okay. You would agree that this patent discloses elongated members that are sutures, correct?

A. I would agree that this patent discloses elongated members, some of which are described as sutures, yes.

Q. Let's go back to claim one, column eight.

A. Yes, sir.

Q. Would you agree with me that the first fiber includes ultra high molecular weight polyethylene?

A. Claim one?

Q. Yes, sir.

A. Yes. It says ultra high molecular weight, high tenacity is the material.

Q. And under this patent, that would include ultra high molecular weight polyethylene?

A. If that's a question, I believe it would, yes.

Q. Okay. And now there's also -- the ultra high molecular weight polyethylene in claim one is braided with a second fiber, correct?

A. That is correct.

Q. And could you look to claim 11?

A. Yes.

Q. And does claim 11 -- would you agree with me that claim 11 says that the second fiber that's braided with the ultra high molecular weight polyethylene is nylon?

A. Yes.

Q. Could you look at claim 12?

A. Yes.

Q. Would you agree with me that that says that the second fiber braided with the ultra high molecular weight polyethylene is polyester?

MR. BONELLA: Object to the form.

THE WITNESS: Yes.

BY MR. SABER:

Q. Is there -- in claim one, is there any mention of a core?

A. No.

Q. In claim 11, is there any mention of a core?

A. No.

together and there's no core, that that's one of the things that falls within claim 11?

MR. BONELLA: Object to the form.

THE WITNESS: Yes.

BY MR. SABER:

Q. Okay. And same thing with respect to claim 12?

A. Yes.

MR. BONELLA: Object to the form.

THE WITNESS: I'm sorry. Yes.

BY MR. SABER:

Q. The -- could you look back at Figure 6?

A. Yes.

Q. Are the -- the various yarns 26 that are shown in Figure 6, are they in direct intertwining contact with each other?

A. It's my opinion that -- yarns 26 as described in --

MR. BONELLA: Object to the form of the question.

MR. SABER: Let me rephrase it.

BY MR. SABER:

Q. Do you agree that the yarns 26 -- that are denoted as 26 in Figure 6?

A. Yes.
Q. Right? That those yarns are in direct intertwining contact as that term is used in the '446 patent?
A. I believe they are, yes.
Q. Let me ask you about Figure 8. Do you see the yarns denoted by the numbers 30?
A. Yes.
Q. Do you agree that the yarns denoted by number 30, Figure 8, are in direct intertwining contact with each other as that term is used in the '446 patent?
A. I believe that they're in direct intertwining contact with each other as sheath yarns. The core yarn is not.
Q. Well, the 30s are all in the sheath, correct?
A. Yes, sir.
Q. Right. And the 30s are not in the core, correct?
A. Yes.
Q. I was asking about the 30s.
A. Yes, sir.
Q. Just so the record is clear, do you agree that the yarns 30 from Figure 8 are in direct

A. I do not have that understanding. I understood your question and that is my answer.

Q. Okay. Assume with me that each one of the yarns -- do you see in Figure 6 there are a dozen or so yarns that are depicted?

A. Yes, sir.

Q. Assume with me that each one of those is a 26.

A. We can do that.

Q. Okay.

A. Yes, sir.

Q. Would you agree with me that at least one of those 26s is ultra high molecular weight polyethylene?

A. Yes.

Q. And do you understand that more than one can be ultra high molecular weight polyethylene?

A. Yes.

Q. And do you have an understanding that one or more of the 26s can be a nonabsorbable yarn?

A. Yes.

Q. Let me turn to the Burgess application, which is Exhibit 7 to your report, your first report.

A. Yes, sir.

question, if I may.

Am I correct that you don't provide an example of a braided construction without direct intertwining contact where there is no core in your report?

MR. BONELLA: Object to form.

BY MR. SABER:

Q. Let me rephrase that again.

A. Yeah, try it again.

Q. In your report am I correct that you provide no example of a braided construction where there is no direct intertwining contact of a -- of a construction that does not have a core?

A. See if this answers your question. I do not believe in my report that I provide in a noncore construction a braid without intertwining contact.

Q. Without direct intertwining contact?

A. Without direct intertwining contact. Is that --

Q. That answers my question.

A. Is that an answer to your question?

Q. Yes, sir, it is.

A. Okay.

Q. And as you sit here today, can you

give me an example of a braided construction which does not have direct intertwining contact where there is no core?

A. I'd have to think about it. I don't know the answer to that.

Q. Okay.

MR. SABER: Why don't we take a break at this point?

THE VIDEOGRAPHER: Going off the record.

The time on the video monitor is 4:04 PM.

(Recess.)

THE VIDEOGRAPHER: Going back on the record. The time on the video monitor is 4:24 PM.

Please continue.

BY MR. SABER:

Q. Dr. Hermes, I'd like to ask you a little bit about the Cohan article, if I'm pronouncing that correctly, which I believe is Exhibit 8 to your report.

A. Yes, sir.

Q. The -- would you -- would you agree with me that the Cohan article discloses the use of ultra high molecular weight PE in a suture

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

DePUY-MITEK, INC.,
A Massachusetts Corporation,
Plaintiff,
vs.
ARTHREX, INC.,
A Delaware Corporation,
Defendants.

ORIGINAL

DAY 2 OF 2

CONTINUED VIDEOTAPED DEPOSITION

OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

July 25, 2006

Reported by:

PAMELA HARRISON, RMR, CRR, CSR

DISK ENCLOSED

marked, for identification purposes, as Defendant's Exhibit-194.) 01:16:47p 01:16:48p

MR. BONELLA: Thank you. 01:17:18p

BY MR. SABER: 01:17:18p

Q. Let me show you Dr. -- or at least the second volume of Dr. Steckel's deposition, and I just want to draw your attention to a couple of pages. 01:17:18p 01:17:23p 01:17:27p 01:17:29p

This is -- we've shown you what's been marked as Defendant's Exhibit-194 which is the second volume of Dr. Steckel's deposition. 01:17:31p 01:17:32p 01:17:35p 01:17:40p

A. And that's what I have, Mr. Saber, thank you. 01:17:40p 01:17:44p

Q. Yes, sir. And if you could look at Page 221 of that? 01:17:44p 01:17:46p

A. Okay. 01:17:48p

Q. You see that there's a discussion of the February 2, 1989, entry from his lab notebook? 01:17:49p 01:17:53p 01:17:56p

A. (Witness reviewing document.) 01:18:20p

Where's the beef? 01:19:22p

Q. Page 221 of his deposition -- 01:19:22p

A. Mm-hmm, okay. 01:19:24p

Q. -- is where that's discussed. Do you 01:19:25p

EXHIBIT 5

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] D04C 1/00

[52] U.S. Cl. 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search 606/228, 230, 231; 87/7, 8, 9; 428/225

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3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
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WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

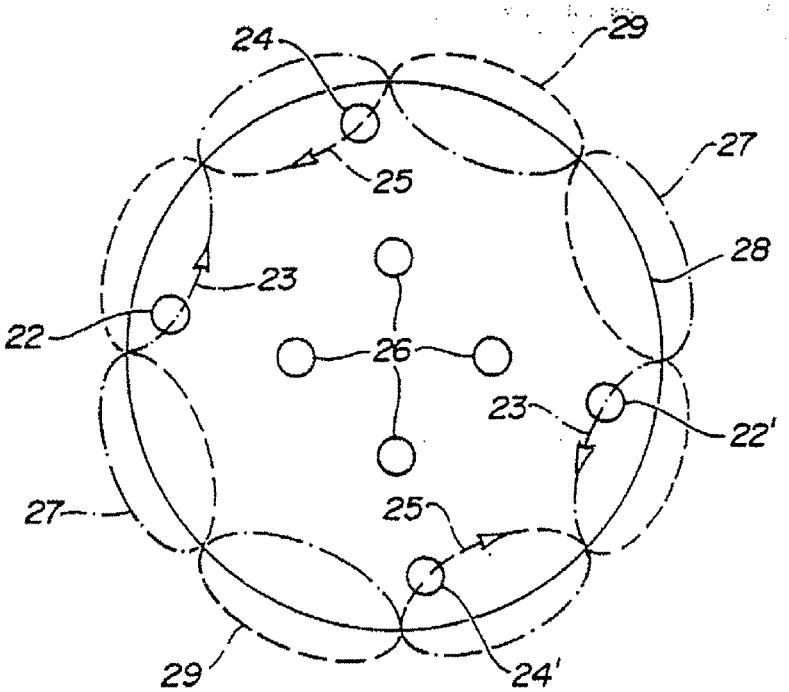
[57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1



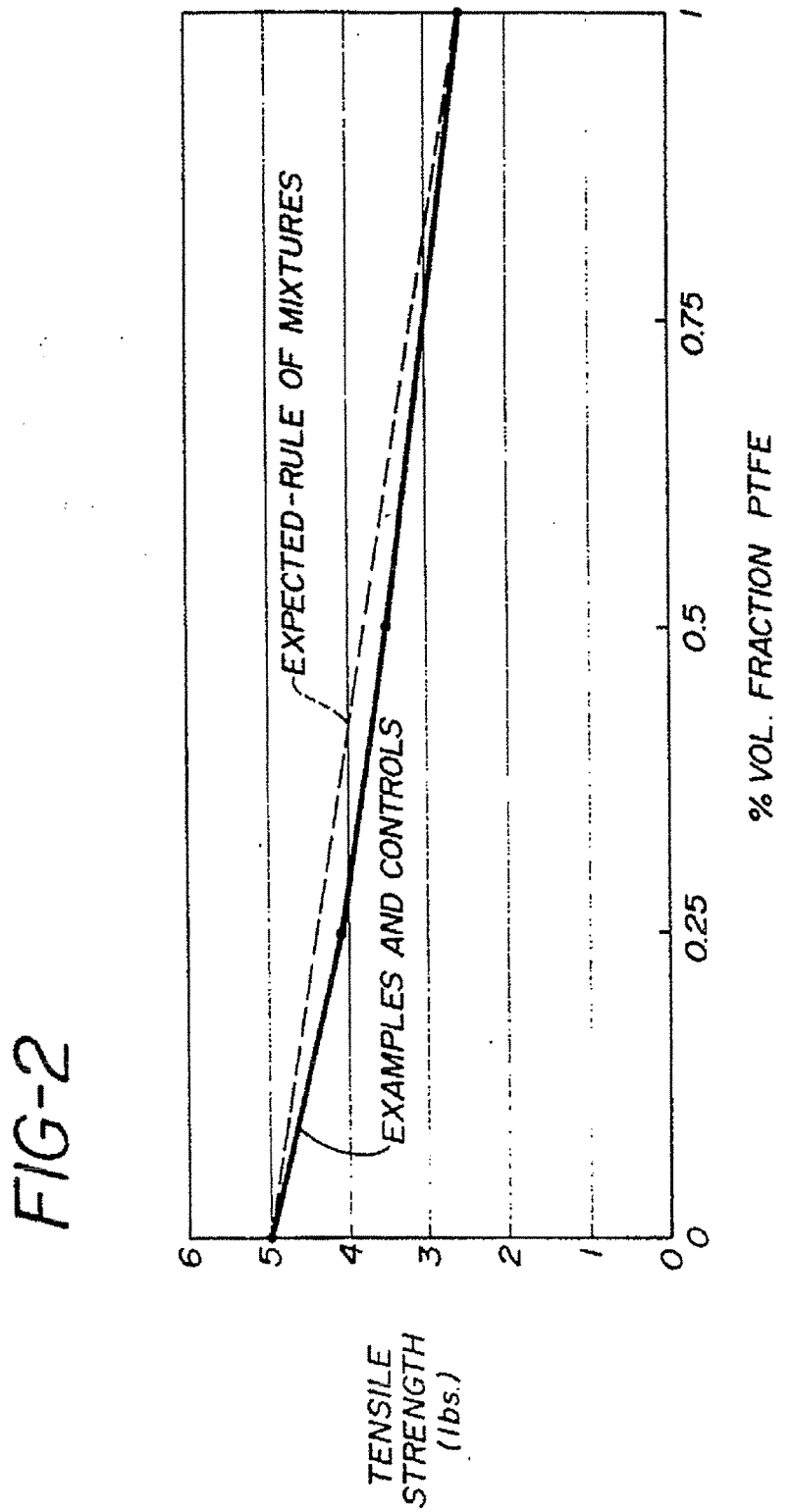
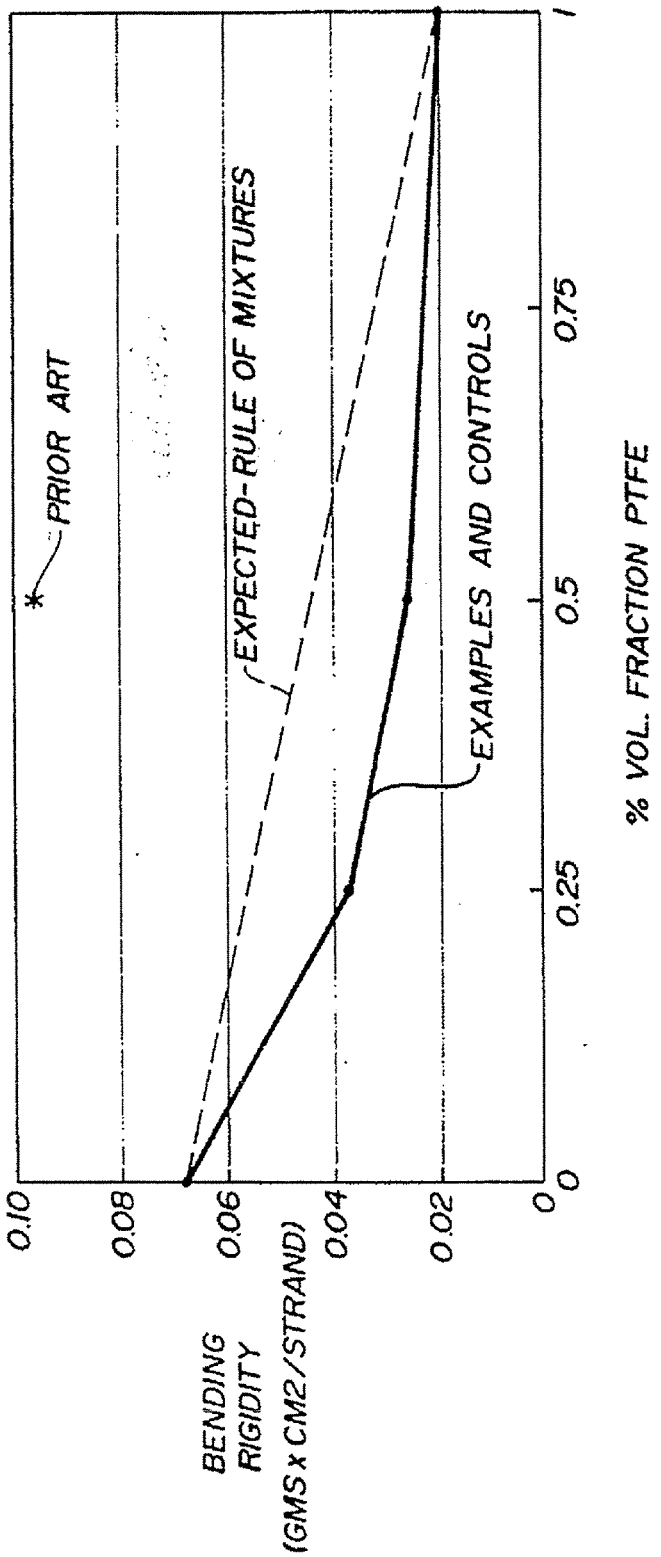

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-2

FIG-3


PRIOR ART
EXPECTED- RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a)(P_a) + (Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

EXHIBIT 6

BOOK NO. 2175

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Page
Book No.
2175

Project No. CBE Experiment No. Date 2/2/89
Subject PET/PTFE COMPOSITE BRAIDS
Purpose EXPLORATORY EVALUATION OF VARIOUS PROCESS METHODOLOGIES

BACKGROUND - PAGE 8

ADDITIONAL PET/PTFE COMPOSITES BRAIDS WERE PRODUCED UTILIZING 1) CARRIER BLEND, 2) YARN BLEND, 3) COMMINGLING TECHNOLOGIES. CONTROLS OF 100% PET AND 100% PTFE WERE ALSO PRODUCED. FIBER SUPPLY/TYPE/DENIER, BRAID CONSTRUCTION, SLEEVE CONDITION, H.S. CONDITIONS WERE CONSTANT FOR ALL BRAIDS.

THE FOLLOWING IS THE YARN INFORMATION/DESCRIPTION:

COMPOSITE BRAID EVALUATION
YARN A DESCRIPTION

MGS ID#	FIBER A	FIB A DENIER	FIB A FILAM COUNT	FIB A SOURCE	FIB A LOT #	FIB A COLOR	FIB A TWIST LEVEL (TPI)	FIB A TWIST DIRCT (S/Z)	FIB A ENTANG LEVEL
CBE-15	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-16	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-16A	PET	70	34	DUPONT		WHIT	0.0	*	R14
CBE-17	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-18	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0
CBE-19	PET	70	48	SUT DEV	SPZ-305	GREN	0.0	*	0

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COMPOSITE BRAID EVALUATION
YARN B DESCRIPTION

MGS ID#	FIBER B	FIB B DENIER	FIB B FILAM COUNT	FIB B SOURCE	FIB B LOT #	FIB B COLOR	FIB B TWIST LEVEL (TPI)	FIB B TWIST DIRCT (S/Z)	FIB B ENTNG LEVEL
CBE-15	PTFE	110	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-16	PTFE	110	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-16A	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-17	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-18	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0
CBE-19	PTFE	115	15	DUPONT	1T138	WHIT	0.0	*	0

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002635

Investigator
Witness Rowland Britt

Date 2/2/89
Date 3-15-90

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Project No. CBE Experiment No. Date 2/2/89

Book No. 2175

Subject PET/PTFE COMPOSITES

Purpose CONTIN.

APPROX. 50/50 BY VOLUME BRAIDS WERE PRODUCED IN THE FOLLOWING CONSTRUCTION + CONDITIONS:

COMPOSITE BRAID EVALUATION
BRAID CONSTRUCTIONS

MGS ID#	COMP TYPE	BRAID TYPE	SIZE	SHxCR CARR.	FIBER A	DEN FIBER A	FIBER A VOLUM FRACT	FIBER B	DEN FIBER B	FIBER B VOLUM FRACT	SH CARR FIB A	SH CARR FIB B	SH CARR FIB C	CR CARR FIB A	CR CA FIB
CBE-15	CB	CS	1	12x1	PET	70	51	PTFE	110	49	DIAGRM	DIAGRM	*	1	1
CBE-16	YB	CS	1	12x1	PET	70	51	PTFE	110	49	1-12	1-12	*	1	1
CBE-16A	YB	CS	1	12x1	PET	70	51	PTFE	115	49	1-12	1-12	*	1	1
CBE-17	CF	CS	1	12x1	PET	70	51	PTFE	115	49	1-12	1-12	*	1	1
CBE-18	CT	CS	1	12x1	PET	70	100	PTFE	115	*	1-12	*	*	1	*
CBE-19	CT	CS	2	12x1	PET	70	*	PTFE	115	100	*	1-12	*	*	1

MS

MS

COMPOSITE BRAID EVALUATION
BRAID PROCESS CONDITIONS

MGS ID#	BRAIDER NO.	GEAR NO.	RPM	SHEATH SPRING DIAM. (MILS)	SHEATH SPRING LENGTH (IN)	CORE TENSION TYPE	CORE TXTRL SET	GLASS ROD PT	CORE TENSION MEAS. (GMS)
CBE-15	12	30	182	0.009		5.0 TXTRL	1.0	Y	16
CBE-16	00	31	215	0.009		5.0 TXTRL	1.0	Y	16
CBE-16A	00	36	215	0.009		5.0 TXTRL	1.0	Y	20
CBE-17	12	32	182	0.009		5.0 TXTRL	0.0	Y	14
CBE-18	12	30	182	0.009		5.0 TXTRL	1.0	Y	17
CBE-19	12	36	182	0.009		5.0 TXTRL	1.0	Y	15

Investigator [signature] Date 2/2/89

Witness Crawford Britt Date 3-15-90

Page

Book No. 2175

Project No. CBE Experiment No. Date 2/2/89

Subject PET/PTFE COMPOSITES

Purpose

CONTINUED

THE ABOVE BRAIDS WERE SCOURED IN SKEIN FORM IN A BEAKER W/ AN AQUEOUS DETERGENT SYSTEM. FOLLOWING SCOURING ONLY, THE BRAIDS WERE HOT-STRETCHED AS FOLLOWS:

COMPOSITE BRAID EVALUATION
HOT STRETCH CONDITIONS

MGS ID#	HOT-STRETCH %	ROLL 1 FPM	ROLL 2 FPM	ROLL 1 # OF WRAPS	ROLL 2 # OF WRAPS	ZONE 1 TEMP (C)	ZONE 2 TEMP (C)	ZONE 3 TEMP (C)	ZONE 4 TEMP (C)
CBE-15	30	9.0	11.7	8	12	125	150	190	225
CBE-16	30	9.0	11.7	8	12	125	150	190	225
CBE-16A	30	9.0	11.7	8	12	125	150	190	225
CBE-17	30	9.0	11.7	8	12	125	150	190	225
CBE-18	30	9.0	11.7	8	12	125	150	190	225
CBE-19	30	9.0	11.7	8	12	125	150	190	225

THE HOT-STRETCHED BRAIDS WERE CHARACTERIZED PER STANDARD SUTURE TEST METHODS:

COMPOSITE BRAID EVALUATION

PHYSICAL PROPERTY CHARACTERIZATION

MGS ID#	USP DIAM (MILS)	ULTIMAT TENSILE STREN (LBS)	INTRIN TENSILE STREN (PSI)	ULTIMAT KNOT STREN (LBS)	INTRIN KNOT STREN (PSI)	KNOT CONVER (%)	ULTIMAT ELONGAT (%)	STRAND BENDING RIGIDITY (GMxCM2)	KNOT STABIL (# THROWS)	BSR CONTL (LBS)	BSR 21 DAY (LBS)	BSR 21 DAY (%)	PICKS PER INCH	TOTAL DENIER
CBE-15	18.6	14.14	51758	9.64	35254	68	34	2.24E-2	5	0.00	0.00		44	2529
CBE-16	19.1	13.07	45460	9.52	33116	73	30	2.20E-2	5	0.00	0.00		45	2694
CBE-16A	0.0	0.00	0	0.00	0	0	0	0.00		0.00	0.00		41	2565
CBE-17	19.9	13.88	44850	11.02	35600	79	39	1.28E-2	5	0.00	0.00			
CBE-18	19.5	21.30	71295	13.54	45241	63	27	3.00E-2	4	0.00	0.00			
CBE-19	20.6	7.37	21460	5.96	17763	79	57	1.12E-2	7	0.00	0.00		39	2970

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

Investigator [signature] Date 2/2/89

Witness Crawford Britt Date 3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002637

Page
Book No. 2175

Project No. CBE Experiment No. Date 2/2/89
Subject PET/PTFE COMPOSITES
Purpose

CONTINUED:

(1) DISCUSSION:

FROM A BRAID PROCESSING VIEWPOINT, THE COMMINGLED YARN WAS THE LEAST PROBLEMATIC BRAID FOLLOWED BY THE YARN BLEND. THE CARRIER BLEND PRESENTED THE MOST DIFFICULTIES IN CONE TOPPING AND BRAID LOOSENESS. THE COMMINGLED YARN DID POSSESS REGIONS WHERE THE YARNS SEPARATED RESULTING IN BRAIDING DIFFICULTY AND ROUGHNESS.

FROM A PROPERTY VIEWPOINT, THE INTRINSIC TENSILES OF THE THREE COMPOSITES WERE CLOSE AND APPROXIMATED A RULE OF MIXTURES AVERAGE OF THE TWO CONTROL BRAIDS. THE CARRIER BLEND WAS APPROX 10% HIGHER. INTRINSIC KNOT STRENGTHS WERE VERY SIMILAR AMONG THE COMPOSITES AND WERE 75-80% OF THE PET CONTROL KNOT STRENGTH. THE COMM. HAD THE HIGHEST KNOT CONVERSION (79%). THE BENDING RIGIDITY OF THE COMMINGLED WAS HALF THE OTHER TWO COMPOSITES, PERHAPS REFLECTING THE MORE HOMOGENEOUS MIXTURE OF THE TWO COMPONENTS. ALL 3 COMPOSITES HAD KNOT SECURITYS OF 5 THROWS - SIGNIFICANTLY BETTER THAN 2 FOR 100% PTFE.

CONFIDENTIAL - NON-PATENT PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002638

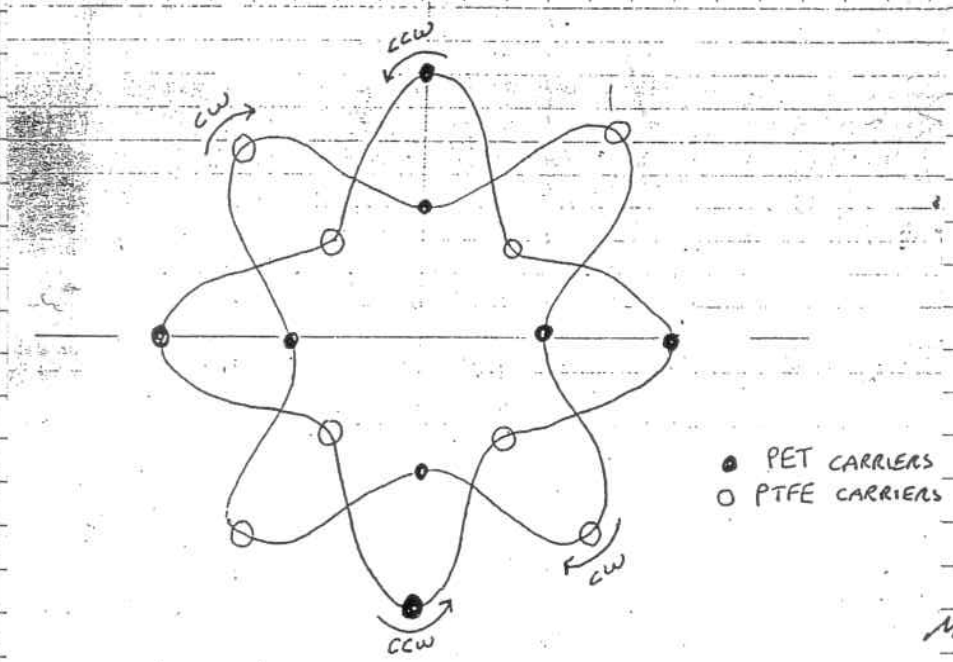
Investigator [signature] Date 2/2/89
Witness Crawford Britt Date 3-15-90

Page
Book No.
2175

Project No. CBE Experiment No. Date 12/13/89
Subject CONTIN - FROM 2125-56
Purpose

PROPERTIES:

THE DIE-DRAWN COMPOSITE BRAID HAD SUPERIOR HANDLING PROPERTIES RELATIVE TO SILK AND ETHIBOND, WHICH IS DEMONSTRATED QUANTITATIVELY IN FIG 2 OF THE KAWABATA BENDING RIGIDITY RESULTS. THE INTRINSIC TENSILE AND KNOT STRENGTHS WERE 87 KSI AND 48 KSI RESPECTIVELY. THE COMPOSITE ALSO RANKED BETTER THAN THE SILK AND ETHIBOND IN KNOT TIE-DOWN, EVEN WITHOUT A COATING.

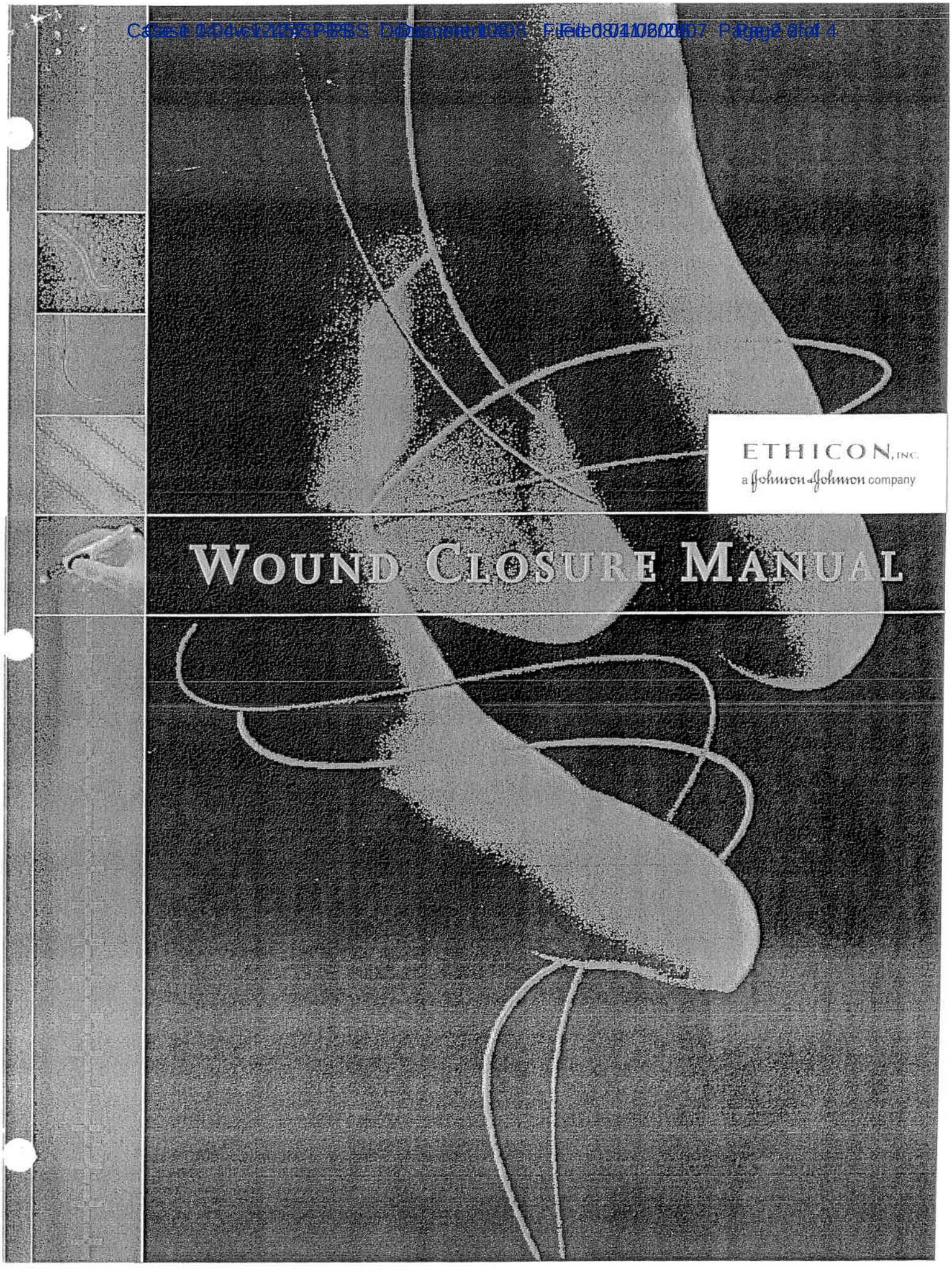


MS 12/13/89

FIG. 1. SCHEMATIC OF CARRIER LAY OUT FOR BALANCED COMPOSITE BRAID.

Investigator Date 12/13/89
Witness Crawford Britt Date 3-15-90

EXHIBIT 7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WOUND CLOSURE MANUAL

procedure, and the type of tissue involved, the surgeon will select suture material that will retain its strength until the wound heals sufficiently to withstand stress on its own.

SUTURE CHARACTERISTICS

The choice of suture materials generally depends on whether the wound closure occurs in one or more layers. In selecting the most appropriate sutures, the surgeon takes into account the amount of tension on the wound, the number of layers of closure, depth of suture placement, anticipated amount of edema, and anticipated timing of suture removal.

Optimal suture qualities include:

1. High uniform tensile strength, permitting use of finer sizes.
2. High tensile strength retention *in vivo*, holding the wound securely throughout the critical healing period, followed by rapid absorption.
3. Consistent uniform diameter.
4. Sterile.
5. Pliable for ease of handling and knot security.
6. Freedom from irritating substances or impurities for optimum tissue acceptance.
7. Predictable performance.

SIZE AND TENSILE STRENGTH

Size denotes the diameter of the suture material. The accepted surgical practice is to use the smallest diameter suture that will adequately hold the mending wounded tissue. This practice minimizes trauma as the suture is passed through the tissue to effect closure. It also ensures that the minimum mass of foreign material is left in the body. Suture size is stated numerically; as the number of 0s in the suture size increases, the diameter of the strand decreases. For example, size 5-0, or 00000, is smaller in diameter than size 4-0, or 0000. The smaller the size, the less tensile strength the suture will have.

Knot tensile strength is measured by the force, in pounds, which the suture strand can withstand before it breaks when knotted. The tensile strength of the tissue to be mended (its ability to withstand stress) determines the size and tensile strength of the suturing material the surgeon selects. The accepted rule is that the tensile strength of the suture need never exceed the tensile strength of the tissue. However, sutures should be at least as strong as normal tissue through which they are being placed.

MONOFILAMENT VS. MULTIFILAMENT STRANDS

Sutures are classified according to the number of strands of which they are comprised. *Monofilament sutures* are made of a single strand of material. Because of their simplified structure, they encounter less resistance as they pass through tissue than multifilament suture material. They also resist harboring organisms which may cause infection.

These characteristics make monofilament sutures well-suited to vascular surgery. Monofilament sutures tie down easily. However, because of their construction, extreme care must be taken when handling and tying these sutures. Crushing or crimping of this suture type can nick or create a weak spot in the strand. This may result in suture breakage.

Multifilament sutures consist of several filaments, or strands, twisted or braided together. This affords greater tensile strength, pliability, and flexibility. Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics. Coated multifilament sutures are well-suited to intestinal procedures.

METRIC MEASURES AND U.S.P. SUTURE DIAMETER EQUIVALENTS

TABLE 1

U.S.P. Size	11-0	10-0	9-0	8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	2	3	4	5	6
Natural Collagen	—	0.2	0.3	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	7.0	8.0	—	—
Synthetic Absorbables	—	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	—
Nonabsorbable Materials	0.1	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	8.0

* Trademark

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WOUND HEALING

SUTURES

NEEDLES

ADHESIVES

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WOUND CLOSURE MANUAL

ETHICON, INC., PO BOX 151, SOMERVILLE, NJ 08876-0151

EXHIBIT 8

US005147383A

United States Patent [19]

Bezwada et al.

[11] Patent Number: 5,147,383

[45] Date of Patent: Sep. 15, 1992

[54] **SUTURE COATED WITH A POLYVINYL ESTER**

[75] Inventors: **Rao S. Bezwada**, Whitehouse Station; **Alastair W. Hunter**, Bridgewater, both of N.J.

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **792,321**

[22] Filed: **Nov. 12, 1991**

Related U.S. Application Data

[62] Division of Ser. No. 473,505, Feb. 1, 1990, Pat. No. 5,089,013.

[51] **Int. Cl.**[5] **A61L 17/00**

[52] **U.S. Cl.** **606/231**; 606/228

[58] **Field of Search** 606/228, 231, 230

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,072,303	3/1937	Herrmann et al.	606/231
3,942,532	3/1976	Hunter et al.	606/231
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4,185,637	1/1980	Mattei	606/230
4,201,216	5/1980	Mattei	606/231 X
4,693,939	9/1987	Ofstead	623/5 X
4,844,067	7/1989	Ikada et al.	606/231
4,983,180	1/1991	Kawai et al.	606/231 X

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Jeffrey A. Schmidt
Attorney, Agent, or Firm—Matthew S. Goodwin

[57] **ABSTRACT**

A surgical suture having a coating thereon of at least one polyvinyl ester, and a method for improving the knot tiedown performance of a suture by first coating a polyvinyl ester solution onto the surface of the suture and then removing the solvent from the coated suture.

11 Claims, No Drawings

SUTURE COATED WITH A POLYVINYL ESTER

This is a division of application Ser. No. 473,505, filed Feb. 1, 1990, U.S. Pat. No. 5,089,013.

BACKGROUND OF THE INVENTION

This invention relates to coated surgical sutures. More specifically, it relates to sutures coated with a vinyl polymer and to a method for improving the knot tiedown performance of a surgical suture.

Surgical sutures often require a surface coating to improve one or more of their performance properties. For example, a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown Performance of the suture, so it passes easily and smoothly through tissue during operative procedures. A monofilament suture may also require a surface coating to reduce the stiff feel of the suture and to increase its pliability.

In response to the need for suitable coatings for surgical sutures, numerous patents have disclosed potential coating compositions. U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,105,034 discloses a multifilament suture coating of a poly(alkylene oxalate), e.g. poly(hexamethylene oxalate). Although the coating compositions disclosed in these patents exhibit excellent handling characteristics and enhance many of the properties of the coated suture, the knot integrity of the coated suture diminishes slightly.

U.S. Pat. No. 3,527,650 discloses a coating of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although PTFE acts as an excellent lubricant to decrease the roughness of multifilament sutures, it has a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application. U.S. Pat. No. 4,043,344 discloses a PLURONICS ™ ethylene oxide/propylene oxide copolymer coating for nonabsorbable surgical sutures. Unfortunately, these copolymer coatings lose their lubricity during wet tiedown evaluations.

In view of the deficiencies with the potential candidates for suture coatings, it would be desirable to develop a coating for a suture that can be applied using conventional techniques, that increases the tactile smoothness of the coated suture without sacrificing its physical properties, and that does not adversely affect the knot integrity of the suture.

SUMMARY OF THE INVENTION

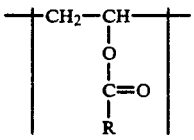
In one aspect, the invention is a suture having its surface coated with an amount of at least one polyvinyl ester effective to improve its knot tiedown performance relative to the knot tiedown performance of the uncoated suture.

In another aspect, the invention is a method of improving the knot tiedown performance of a suture. This method comprises the steps of coating the surface of the suture with an effective amount of a solution of at least one polyvinyl ester in an organic solvent, and then removing the solvent from the coated suture.

The polyvinyl ester coating of this invention can be applied to the surface of a suture using conventional techniques. The knot tiedown performance of the coated suture, which is an indication of its tactile smoothness, dramatically improves without sacrificing the tensile properties of the coated suture. Surprisingly, these improvements in properties are acheived without adversely affecting the knot security of the coated suture.

DETAILED DESCRIPTION OF THE INVENTION

Polyvinyl (Pv) esters within the scope of this invention are known and can be prepared by conventional techniques, for example, by polymerizing a vinyl ester monomer using a free radical initiation process. Preferably, the PV ester is represented by repeating units of the formula:



wherein R is C_{6-30} straight or branched alkyl.

If the alkyl group of the formula above were to have less than 10 carbons, then the ester would not typically exhibit good coating properties. If the alkyl group were to have greater than 30 carbons, then the availability and purity of the ester would typically not be desirable for coating applications Preferably, R is C_{14-18} straight alkyl. The most preferred PV ester is polyvinyl stearate.

The amount of PV ester coated onto the surface of the suture to improve knot tiedown performance will generally depend on the molecular weight of the PV ester and can readily be determined empirically. In most instances, the required amount of PV ester decreases as its molecular weight increases. Advantageously, the amount of PV ester coated onto the suture ranges from about 0.3 to about 20, preferably from about 0.5 to about 15 percent of the weight of the coated suture. Generally, amounts greater than 20 weight percent may compromise the knot security of the coated suture and amounts below 0.3 weight percent may fail to achieve any significant improvement in suture properties. The suture can be coated with not only one PV ester, but also a mixture of 2 or more PV esters, if desired. Preferably, the suture is coated with one PV ester.

The PV ester coatings of this invention are typically characterized by a weight average molecular weight as determined by gel permeation chromatography ranging from about 50,000 to about 2,000,000, preferably from about 100,000 to about 1,000,000, and most perferably from about 200,000 to about 500,000. A PV ester with molecular weight below 50,000 may fail to significantly improve the knot tiedown of a coated suture, and a PV ester with molecular weight above 2,000,000 may increase the stiffness of the coated suture.

Sutures within the scope of this invention can be of any type used or contemplated for operative procedures. The suture can be synthetic or natural, absorbable or nonabsorbable, or a monofilament or multifilament in a braided, twisted or covered form. In addition, the sutures can be attached to one or more needles, if desired. Examples of absorbable monofilament sutures include natural sutures such as surgical gut and collagen, and synthetic sutures such as homopolymers and copolymers of p-dioxanone. Examples of absorbable multifilament sutures include sutures prepared from polymers of one or more lactones, e.g. VICRYL ®

poly(lactide-co-glycolide) multifilament suture. Examples of nonabsorbable monofilament and multifilament sutures include nylon, polypropylene, steel, polyvinylidene fluoride, linen, cotton, silk, and polyesters such as polyethylene terephthalate (PET). The preferred sutures are nonabsorbable, multifilament sutures, preferably polyester sutures. The most preferred suture is PET.

The organic solvent for the PV ester coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane and aromatic solvents such as toluene.

The coating can easily be prepared by simply dissolving the PV ester into the appropriate organic solvent. The concentration of the ester in solution will, of course, depend on the amount of PV ester desirably coated onto the surface of the suture, but generally should range from about 3 to about 20, preferably from about 5 to about 15 weight percent.

Once a solution of the PV ester is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temperature under vacuum.

The organic solvent and the preparation of a coating solution for application is normally required for coating multifilament sutures. However, an alternative approach is feasible for coating monofilament sutures without requiring the preparation of coating solution. If a synthetic monofilament suture is to be coated, then the fiber-forming polymer from which the suture is derived could be coextruded with a suitably low molecular weight PV ester so that the ester could exude to the surface of the fiber during extrusion to increase its tactile smoothness. Such methods have been demonstrated to enhance the lubricity and knotting characteristics of the fiber-forming polymer.

The PV ester in preferred embodiments of this invention is an essentially nonabsorbable, water insoluble, waxy solid. However, the ester can be modified or additives can be incorporated into the coating composition to tailor coating properties for specific applications. For example, the ester can be made water soluble by copolymerizing the ester with a polyvinyl alcohol and/or polyvinyl pyrrolidone. Alternatively, a vinyl alcohol ester could be copolymerized with vinyl alcohol and/or vinyl pyrrolidone. A bioabsorbable ester especially suited for absorbable sutures can be prepared by first functionalizing a low molecular weight PV ester, and then copolymerizing it with one or more lactones, e.g. glycolide, e-caprolactone, lactide, p-dioxanone, and the like. Similarly, silicone lubricating agents such as polydimethylsiloxane resins and elastomers, as well as other known polymeric coatings such as homopolymers and copolymers of p-dioxanone and PLURONICS TM ethylene oxide/propylene oxide copolymers, can be added to the coating composition to modify or enhance the final properties of the coated suture. All of these embodiments, as well as similar embodiments to modify or enhance the coated suture properties, are well within the scope of the claimed invention.

Although the PV ester has been described as a coating for surgical sutures, noncoating applications can be readily envisioned. For example, the PV ester may be used as a slip agent in thermo-dye transfer processes, as an elastomeric component for polyester molding compounds for bumpers and dashboards of automobiles, as a component in tissue adhesives for dentistry and surgery and as a component in jet printing ink applications.

The following example illustrates but is in no way intended to limit the scope of the claimed invention. In the example, the tensile properties, tiedown roughness and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. The straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The tiedown roughness is a measure of the knot tiedown performance. It provides an indication of the force required to slide a knot down a suture, and it is determined generally according to the procedure described in U.S. Pat. No. 3,942,532. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping.

EXAMPLE

For each of three runs, a solution of polyvinyl stearate with a weight average molecular weight of 239,000 and a melting temperature of 48° C. in toluene is prepared. A size 2/0 (USP standard) MERSILENE® PET braided multifilament suture is coated at room temperature with the coating solution using conventional laboratory coating equipment, and the coated suture is subsequently dried in air at 110° F. to remove the toluene. Table 1 compares the tensile and tiedown roughness properties and the knot security characteristics for each of the three runs with an uncoated MERSILENCE® PET braided multifilament suture.

TABLE 1

PROPERTIES OF POLYESTER SUTURE COATED WITH POLYVINYL STEARATE (PVS)

	PVS COATING CONCENTRATION IN TOLUENE, WT. PERCENT			UNCOATED SUTURE
	5.15	8.10	12.15	CONTROL
Percent Solids[1], wt.	0.97	1.74	5.20	—
Suture Diameter, mils.	13.60	13.64	13.93	13.23
Dry Tiedown Roughness, gms.	140.4	127.8	118.6	355.5
Wet[2] Tiedown Roughness, gms.	126.2	135.4	137.1	249.2
Wet Knot Security	4	4	4	4
Dry Knot Tensile Strength, psi	52,567	51,973	50,232	52,458
Wet Knot Tensile Strength, psi	53,971	54,452	48,832	56,794
Dry Straight Tensile Strength, psi	94,882	94,235	91,994	102,946
Percent Elongation	14.70	15.00	16.30	16.27

[1]Determined by measuring the difference in weight between the coated and uncoated suture.
[2]Wet properties are determined after soaking the suture in water at 25° C. for at least 24 hours.

The results indicate that the polyester suture coated with a varying amount of Polyvinyl stearate exhibits significantly improved dry and wet tiedown roughness relative to that of the uncoated suture. The improved roughness is acheived without sacrificing knot security or the tensile properties of the uncoated suture. Gener-

ally, a wet tiedown roughness of less than 200 grams, preferably less than 150 grams, for the coated sutures of this invention can be readily obtained.

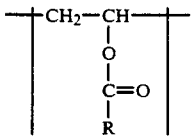
Similar outstanding results can be obtained with other PV ester coatings within the scope of the claimed invention.

We claim:

1. A suture wherein the outer surface thereof is coated with at least one homopolymer of a vinyl ester monomer in an amount between about 0.3 to about 20 percent of the weight of the coated suture.

2. The suture of claim **1** wherein the surface thereof is coated with one homopolymer of a vinyl ester monomer.

3. The suture of claim **2** wherein the homopolymer is represented by repeating units of the formula:



where R is C_{6-30} straight or branched alkyl.

4. The suture of claim **3** wherein R is C_{14-18} straight alkyl.

5. The suture of claim **4** wherein the homopolymer is polyvinyl steasrate.

6. The issue of claim **5** wherein the molecular weight of the homopolymer is between about 200,00 and about 500,000.

7. The suture of claim **6** wherein the he suture is a monofilament or multifilament suture with or without one or more needles.

8. The suture of claim **7** wherein the he suture is a multifilament suture.

9. The suture of claim **8** wherein he multifilament suture is an nonabsorbable suture.

10. The suture of claim **9** wherein the he suture is a polyester.

11. The suture of claim **10** wherein the polyester is polyethylene terephthalate.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,147,383

DATED : September 15, 1992

INVENTOR(S) : Rao S. Bezwada and Alastair W. Hunter

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6:

In claim 5 "steasrate" should be -- stearate --.

In claim 6, "issue" should be -- suture --.

In claim 7, "he" should be eliminated.

In claim 8, "he" should be eliminated.

In claim 9, "he" should be -- the --.

In claim 10, "he" should be eliminated.

Signed and Sealed this

Nineteenth Day of October, 1993

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

EXHIBIT 9

US005089013A

United States Patent [19]

Bezwada et al.

[11] Patent Number: 5,089,013

[45] Date of Patent: Feb. 18, 1992

[54] **SUTURE COATED WITH A POLYVINYL ESTER**

[75] Inventors: **Rao S. Bezwada**, Whitehouse Station; **Alastair W. Hunter**, Bridgewater, both of N.J.

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **473,505**

[22] Filed: **Feb. 1, 1990**

[51] **Int. Cl.**[5] **A61L 17/00**; A01N 1/02; A61K 1/02

[52] **U.S. Cl.** **606/228**; 606/231; 427/2

[58] **Field of Search** 606/228, 229, 230, 231; 427/2; 623/5; 604/368

[56] **References Cited**

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4,027,676	6/1977	Mattei	606/231 X
4,034,344	8/1977	Landi et al. .	
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4,124,748	11/1978	Fujimoto et al.	604/368 X
4,155,893	5/1979	Fujimoto et al.	604/368 X
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4,589,873	5/1986	Schwartz et al.	427/2 X
4,693,939	9/1987	Ofstead	623/5 X
4,711,241	12/1987	Lehmann .	
4,844,067	7/1989	Ikada et al.	427/2 X

Primary Examiner—David J. Isabella
Assistant Examiner—Elizabeth M. Burke
Attorney, Agent, or Firm—Matthew S. Goodwin

[57] **ABSTRACT**

A surgical suture having a coating thereon of at least one polyvinyl ester, and a method for improving the knot tiedown performance of a suture by first coating a polyvinyl ester solution onto the surface of the suture and then removing the solvent from the coated suture.

4 Claims, No Drawings

SUTURE COATED WITH A POLYVINYL ESTER

BACKGROUND OF THE INVENTION

This invention relates to coated surgical sutures. More specifically, it relates to sutures coated with a vinyl polymer and to a method for improving the knot tiedown performance of a surgical suture.

Surgical sutures often require a surface coating to improve one or more of their performance properties. For example, a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture, so it passes easily and smoothly through tissue during operative procedures. A monofilament suture may also require a surface coating to reduce the stiff feel of the suture and to increase its pliability.

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U.S. Pat. No. 3,527,650 discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although PTFE acts as an excellent lubricant to decrease the roughness of multifilament sutures, it has a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application. U.S. Pat. No. 4,043,344 discloses a PLURONICS ethylene oxide/propylene oxide copolymer coating for nonabsorbable surgical sutures. Unfortunately, these copolymer coatings lose their lubricity during wet tiedown evaluations.

In view of the deficiencies with the potential candidates for suture coatings, it would be desirable to develop a coating for a suture that can be applied using conventional techniques, that increases the tactile smoothness of the coated suture without sacrificing its physical properties, and that does not adversely affect the knot integrity of the suture.

SUMMARY OF THE INVENTION

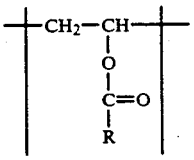
In one aspect, the invention is a suture having its surface coated with an amount of at least one polyvinyl ester effective to improve its knot tiedown performance relative to the knot tiedown performance of the uncoated suture.

In another aspect, the invention is a method of improving the knot tiedown performance of a suture. This method comprises the steps of coating the surface of the suture with an effective amount of a solution of at least one polyvinyl ester in an organic solvent, and then removing the solvent from the coated suture.

The polyvinyl ester coating of this invention can be applied to the surface of a suture using conventional techniques. The knot tiedown performance of the coated suture, which is an indication of its tactile smoothness, dramatically improves without sacrificing the tensile properties of the coated suture. Surprisingly, these improvements in properties are acheived without adversely affecting the knot security of the coated suture.

DETAILED DESCRIPTION OF THE INVENTION

Polyvinyl (PV) esters within the scope of this invention are known and can be prepared by conventional techniques, for example, by polymerizing a vinyl ester monomer using a free radical initiation process. Preferably, the PV ester is represented by repeating units of the formula:



wherein R is C_{6-30} straight or branched alkyl.

If the alkyl group of the formula above were to have less than 10 carbons, then the ester would not typically exhibit good coating properties. If the alkyl group were to have greater than 30 carbons, then the availability and purity of the ester would typically not be desirable for coating applications. Preferably, R is C_{14-18} straight alkyl. The most preferred PV ester is polyvinyl stearate.

The amount of PV ester coated onto the surface of the suture to improve knot tiedown performance will generally depend on the molecular weight of the PV ester and can readily be determined empirically. In most instances, the required amount of PV ester decreases as its molecular weight increases. Advantageously, the amount of PV ester coated onto the suture ranges from about 0.3 to about 20, preferably from about 0.5 to about 15 percent of the weight of the coated suture. Generally, amounts greater than 20 weight percent may compromise the knot security of the coated suture and amounts below 0.3 weight percent may fail to achieve any significant improvement in suture properties. The suture can be coated with not only one PV ester, but also a mixture of 2 or more PV esters, if desired. Preferably, the suture is coated with one PV ester.

The PV ester coatings of this invention are typically characterized by a weight average molecular weight as determined by gel permeation chromatography ranging from about 50,000 to about 2,000,000, preferably from about 100,000 to about 1,000,000, and most perferably from about 200,000 to about 500,000. A PV ester with molecular weight below 50,000 may fail to significantly improve the knot tiedown of a coated suture, and a PV ester with molecular weight above 2,000,000 may increase the stiffness of the coated suture.

Sutures within the scope of this invention can be of any type used or contemplated for operative procedures. The suture can be synthetic or natural, absorbable or nonabsorbable, or a monofilament or multifilament in a braided, twisted or covered form. In addition, the sutures can be attached to one or more needles, if desired. Examples of absorbable monofilament sutures include natural sutures such as surgical gut and collagen, and synthetic sutures such as homopolymers and copolymers of p-dioxanone. Examples of absorbable multifilament sutures include sutures prepared from fiber-forming polymers of one or more lactones, e.g. VICRYL® poly(lactide-co-glycolide) multifilament

suture. Examples of nonabsorbable monofilament and multifilament sutures include nylon, polypropylene, steel, polyvinylidene fluoride, linen, cotton, silk, and polyesters such as polyethylene terephthalate (PET). The preferred sutures are nonabsorbable, multifilament sutures, preferably polyester sutures. The most preferred suture is PET.

The organic solvent for the PV ester coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane and aromatic solvents such as toluene.

The coating can easily be prepared by simply dissolving the PV ester into the appropriate organic solvent. The concentration of the ester in solution will, of course, depend on the amount of PV ester desirably coated onto the surface of the suture, but generally should range from about 3 to about 20, preferably from about 5 to about 15 weight percent.

Once a solution of the PV ester is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temPerature under vacuum.

The organic solvent and the preparation of a coating solution for application is normally required for coating multifilament sutures. However, an alternative approach is feasible for coating monofilament sutures without requiring the preparation of coating solution. If a synthetic monofilament suture is to be coated, then the fiber-forming polymer from which the suture is derived could be coextruded with a suitably low molecular weight PV ester so that the ester could exude to the surface of the fiber during extrusion to increase its tactile smoothness. Such methods have been demonstrated to enhance the lubricity and knotting characteristics of the fiber-forming polymer.

The PV ester in preferred embodiments of this invention is an essentially nonabsorbable, water insoluble, waxy solid. However, the ester can be modified or additives can be incorporated into the coating composition to tailor coating properties for specific applications. For example, the ester can be made water soluble by copolymerizing the ester with a polyvinyl alcohol and/or polyvinyl pyrrolidone. Alternatively, a vinyl alcohol ester could be copolymerized with vinyl alcohol and/or vinyl pyrrolidone. A bioabsorbable ester especially suited for absorbable sutures can be prepared by first functionalizing a low molecular weight PV ester, and then copolymerizing it with one or more lactones, e.g. glycolide, ϵ-Caprolactone, lactide, p-dioxanone, and the like. Similarly, silicone lubricating agents such as polydimethylsiloxane resins and elastomers, as well as other known polymeric coatings such as homopolymers and copolymers of p-dioxanone and PLURONICS ethylene oxide/propylene oxide copolymers, can be added to the coating composition to modify or enhance the final properties of the coated suture. All of these embodiments, as well as similar embodiments to modify or enhance the coated suture properties, are well within the scope of the claimed invention.

Although the PV ester has been described as a coating for surgical sutures, noncoating applications can be readily envisioned. For example, the PV ester may be used as a slip agent in thermo-dye transfer processes, as an elastomeric component for polyester molding compounds for bumpers and dashboards of automobiles, as a component in tissue adhesives for dentistry and surgery and as a component in jet printing ink applications.

The following example illustrates but is in no way intended to limit the scope of the claimed invention. In the example, the tensile properties, tiedown roughness and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The tiedown roughness is a measure of the knot tiedown performance. It provides an indication of the force required to slide a knot down a suture, and it is determined generally according to the procedure described in U.S. Pat. No. 3,942,532. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping.

EXAMPLE

For each of three runs, a solution of polyvinyl stearate with a weight average molecular weight of 239,000 and a melting temperature of 48° C. in toluene is prepared. A size 2/0 (USP standard) MERSILENE® PET braided multifilament suture is coated at room temperature with the coating solution using conventional laboratory coating equipment, and the coated suture is subsequently dried in air at 110° F. to remove the toluene. Table 1 compares the tensile and tiedown roughness properties and the knot security characteristics for each of the three runs with an uncoated MERSILENE PET braided multifilament suture.

TABLE 1

PROPERTIES OF POLYESTER SUTURE COATED WITH POLYVINYL STEARATE (PVS)

	PVS COATING CONCENTRATION IN TOLUENE, WT. PERCENT			UNCOATED SUTURE
	5.15	8.10	12.15	CONTROL
Percent Solids[1], wt.	0.97	1.74	5.20	—
Suture Diameter, mils.	13.60	13.64	13.93	13.23
Dry Tiedown Roughness, gms.	140.4	127.8	118.6	355.5
Wet Tiedown Roughness, gms.	126.2	135.4	137.1	249.2
Wet Knot Security	4	4	4	4
Dry Knot Tensile Strength, psi	52,567	51,973	50,232	52,458
Wet Knot Tensile Strength, psi	53,971	54,452	48,832	56,794
Dry Straight Tensile Strength, psi	94,882	94,235	91,994	102,946
Percent Elongation	14.70	15.00	16.30	16.27

[1]Determined by measuring the difference in weight between the coated and uncoated suture.
[2]Wet properties are determined after soaking the suture in water at 25° C. for at least 24 hours.

The results indicate that the polyester suture coated with a varying amount of polyvinyl stearate exhibits significantly improved dry and wet tiedown roughness relative to that of the uncoated suture. The improved roughness is achieved without sacrificing knot security or the tensile properties of the uncoated suture. Gener-

ally, a wet tiedown roughness of less than 200 grams, preferably less than 150 grams, for the coated sutures of this invention can be readily obtained.

Similar outstanding results can be obtained with other PV ester coatings within the scope of the claimed invention.

We claim:

1. A method of improving the knot tiedown performance of a suture comprising the steps of:

a) coating an outer surface of the suture with a solution of at least one homopolymer of a vinyl ester monomer in an organic solvent, and then

b) removing the solvent from the coated suture so as to coat the suture with an amount of the homopolymer from 0.3 to 20 percent of the weight of the coated suture.

2. The method of claim 1 wherein the solution of the homopolymer of a vinyl ester monomer is a solution of between 0.5 to 15 weight percent of the homopolymer in toluene.

3. The method of claim 2 wherein the solvent is removed by drying the coated surface in air.

4. The method of claim 3 wherein the coated suture is dried at a temperature greater than room temperature.

* * * * *

EXHIBIT 10

United States Patent [19]

Bezwada et al.

[11] **Patent Number: 4,994,074**

[45] **Date of Patent: Feb. 19, 1991**

[54] **COPOLYMERS OF EPSILON-CAPROLACTONE, GLYCOLIDE AND GLYCOLIC ACID FOR SUTURE COATINGS**

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[73] Assignee: **Ethicon, Inc.,** Somerville, N.J.

[21] Appl. No.: **473,291**

[22] Filed: **Feb. 1, 1990**

[51] **Int. Cl.**[5] **C08G 63/06;** C08G 63/08

[52] **U.S. Cl.** **606/230;** 528/354

[58] **Field of Search** 528/354; 606/230, 228, 606/231

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4,791,929	12/1980	Jarret et al. .	

Primary Examiner—Earl Nielsen

Attorney, Agent, or Firm—Matthew S. Goodwin

[57] **ABSTRACT**

Copolymer of a predominant amount of ϵ-caprolactone, the balance being glycolide and glycolic acid. Coating for an absorbable, multifilament surgical suture prepared by dissolving the copolymer in an organic solvent.

16 Claims, No Drawings

COPOLYMERS OF EPSILON-CAPROLACTONE, GLYCOLIDE AND GLYCOLIC ACID FOR SUTURE COATINGS

BACKGROUND OF THE INVENTION

This invention relates to copolymers of ϵ-caprolactone and glycolide, and more specifically, to such copolymers with improved properties especially adapted for use as coatings for absorbable multifilament surgical sutures.

Multifilament surgical sutures such as Vicryl® poly(lactide-co-glycolide) multifilament suture typically require a surface coating to improve the pliability and knotting characteristics of the suture. A polymer coating which has recently been developed and shows significant promise as a suture coating is derived from a polymer solution of ϵ-caprolactone in an appropriate organic solvent. The coating solution is typically applied to the surface of the suture using conventional techniques, and then the solvent is removed. Polycaprolactone is a biocompatable polymer with a relatively low melting point, a property which is essential for good coating characteristics. Additionally, sutures coated with polycaprolactone exhibit enhanced pliability and handling characteristics. Unfortunately, polycaprolactone homopolymer is essentially nonabsorbable because it retains some of its mass and mechanical integrity in vivo for periods up to one year, which is too long for numerous surgical applications.

In an effort to improve the bioabsorbability and other properties of a polycaprolactone coating polymer, the polymer composition has been modified by incorporating copolymerizable monomers or lubricating agents therein. For example, U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare polymer fibers or coatings for multifilament sutures. U.S. Pat. No 4,791,929 discloses a bioabsorbable coating of a copolymer of at least 50 percent ϵ-caprolactone and glycolide. Sutures coated with such copolymers are reported to be less stiff than sutures coated with other materials, and the physical properties of the coated suture are also reported to be acceptable.

Unfortunately, the problem of adequate bioabsorbability of homopolymers and copolymers of ϵ-caprolactone for suture coating applications still remains. One of the difficulties a skilled polymer chemist has faced in solving this problem is in developing a faster absorbing polymer of ϵ-caprolactone without sacrificing the physical properties of multifilament sutures coated with such a polymer. In view of the deficiencies with the known art polycaprolactone coatings, it would be most desirable to accomplish this goal.

SUMMARY OF THE INVENTION

In one aspect, the invention is a copolymer of a predominant amount of ϵ-caprolactone, and the balance glycolide and glycolic acid. The copolymer is characterized by a concentration of glycolic acid such that the intrinsic viscosity of the copolymer in hexafluoroisopropyl alcohol (HFIP) is between about 0.15 to about 0.60 deciliters per gram (dl/g).

In another aspect, the invention is a coating for a surgical suture. This coating comprises a solution of the copolymer described above in an organic solvent.

Surprisingly, the use of glycolic acid as a comonomer into the copolymers of this invention increases the rate of absorption of the copolymers relative to the absorption rate of prior art copolymers of ϵ-caprolactone and glycolide. This increase in the rate of absorption is achieved while maintaining the physical properties of sutures coated with such copolymers, for example, tissue drag, which measures the degree of trauma associated with passing the coated suture through tissue, knot tiedown characteristics and tensile properties.

The copolymers of this invention and the coatings derived therefrom can be used for coating bioabsorbable, multifilament surgical sutures.

DETAILED DESCRIPTION OF THE INVENTION

A predominant amount of ϵ-caprolactone generally refers to an amount of ϵ-caprolactone greater than 50 mole percent of the comonomer composition from which the copolymer of this invention is derived. ϵ-Caprolactone is the predominant component of the copolymer because of its low melting temperature and its ability to enhance the physical properties of coated multifilament sutures. Preferably, the amount of ϵ-caprolactone used ranges from about 80 to about 95, more preferably from about 90 to about 95 mole percent.

The remaining comonomers of the copolymer of this invention are glycolide and glycolic acid. The amount of glycolic acid in the comonomer composition from which the copolymer is derived is an amount such that the intrinsic viscosity of the copolymer in a 0.1 g/dl solution of HFIP at 25° C. is between about 0.15 to about 0.60 dl/g. Preferably, the intrinsic viscosity of the copolymer is between about 0.20 to about 0.50 dl/g. The glycolic acid can be used in part to control the molecular weight of the copolymer, and therefore its intrinsic viscosity, and, in combination with the glycolide comonomer, can be used to lower the melting temperature of the copolymer relative to that of a polycaprolactone homopolymer. Advantageously, the crystalline melting temperature of the copolymer is between about 30° to about 60° C., preferably between about 35° to about 50° C. The frequency of the hydrolytically labile linkages associated with the use of glycolic acid along the chains of the copolymer is also responsible for enhancing the absorption profile of the coating.

The adjustment of the intrinsic viscosity of the copolymer by varying the concentration of glycolic acid is important to achieve a copolymer coating that will not only form a film on the outer surface of the suture but also penetrate and distribute evenly into the interstices of the multifilament fibers. This penetration and the subsequent adsorption of the coating polymer onto individual fibers of the multifilament increases the pliability of the suture and enhances its knotting characteristics, specifically the ease with which a knot can slide down the length of the suture during an operative procedure. Likewise, the control of the crystalline melting temperature, which to a significant degree is controlled by the intrinsic viscosity, by varying the relative proportions of glycolide and glycolic acid is important to achieve similar improvements in the properties of coated sutures.

Advantageously, the amount of glycolic acid in the comonomer composition from which the copolymer is derived to achieve an acceptable intrinsic viscosity and to increase the rate of absorption relative to the prior art copolymers of ϵ-caprolactone and glycolide ranges from about 1 to about 15, preferably from about 2 to about 10 mole percent. The glycolide comonomer not only lowers the melting temperature of the copolymer, but also, to a lesser extent relative to glycolic acid, increases the rate of absorption and is preferably present in the comonomer composition at a concentration ranging from about 5 to about 20, more preferably from about 5 to about 10 mole percent. The mole ratio of glycolide to glycolic acid to achieve desired coating properties advantageously ranges from about 20:80 to about 95:5, preferably from about 70:30 to about 90:10.

The copolymers of this invention can be prepared by polymerizing in the presence of an organometallic catalyst the desired amounts of ϵ-caprolactone, glycolide and glycolic acid at an elevated temperature, e.g. 160° to 190° C., for a time sufficient to achieve the desired intrinsic viscosity. The organometallic catalyst is preferably a tin-based catalyst, preferably stannous octoate, and is present in the reaction mixture at a mole ratio of monomer to catalyst between 10,000 to 90,000 to 1, preferably 15,000 to 30,000 to 1.

The organic solvent for the polymer coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane, aromatic solvents such as toluene, and aliphatic ketones such as acetone.

The coating can easily be prepared by simply dissolving the copolymer of this invention into the appropriate organic solvent. The concentration of the copolymer in solution desirably ranges from about 1 to about 20, preferably from about 10 to about 15 weight percent. Generally, concentrations greater than 20 weight percent polymer provide coating solutions which are too viscous to achieve adequate penetration of the coating solution into the interstices of the fibers, and concentrations below 1 weight percent are inadequate to properly coat a sufficient amount of copolymer onto the suture, although it may be possible but inconvenient to employ two or more coating steps to achieve a sufficient coating concentration on the copolymer. Once a solution of the copolymer is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temperature under vacuum.

The suture to be coated can be a monofilament or multifilament suture. Preferably, a multifilament suture in a braided, twisted, crocheted, knitted or covered form is used. Preferably, the suture is an absorbable, multifilament braided suture. The preferred absorbable sutures are those prepared from a polymer of a lactone or a polymer of one or more lactones Examples of the most widely used lactones for suture preparation are lactide, glycolide and ϵ-caprolactone. The most preferred suture is Vicryl® poly(lactide-co-glycolide) multifilament braided suture. For numerous surgical applications, the suture is attached to one or more needles.

The following examples illustrate the claimed invention and are in no way intended to limit its scope.

EXAMPLE 1

COPLYOMER OF ϵ-CAPROLACTONE/GLYCOLIDE/GLYCOLIC ACID AT 0.90/0.05/0.10 MOLE RATIO

A flame dried, 250 ml, round bottom single neck flask is charged with 102.73 g (0.9 mole) of ϵ-caprolactone, 5.80 g (0.05 mole) of glycolide, 7.61 g (0.10 mole) of glycolic acid, and 0.121 milliliters of stannous octoate (0.33 molar in toluene). The flask is fitted with a flame dried mechanical stirrer. The reactor is purged with nitrogen three times before venting with nitrogen. The reaction mixture is heated to 160° C. and maintained at this temperature for 24 hours. The copolymer is isolated, characterized, and tested for absorption. The results are reported in Table 1.

EXAMPLE 2

COPOLYMER OF ϵ-CAPROLACTONE/GLYCOLIDE/GLYCOLIC ACID AT 0.90/0.08/0.04 BY MOLE

The procedure of Example 1 is repeated, except that the reaction flask is charged with 9.29 g (0.08 mole) of glycolide and 3.04 g (0.04 mole) of glycolic acid.

COMPARATIVE EXAMPLE 1

COPOLYMER OF ϵ-CAPROLACTONE/GLYCOLIDE AT 90/10 BY WT. (90/10 BY MOLE)

A flame dried, 250 ml, round bottom, single neck flask is charged with 90 g (0.789 mole) of ϵ-caprolactone, 10 g (0.0862 mole) of glycolide, 7.96 ml (40 millimole/mole of total monomer) of distilled 1-dodecanol, and 0.121 ml of stannous octoate (0.33 molar solution in toluene). The reaction flask is purged with nitrogen three times before venting with nitrogen. The reaction mixture is heated to 180° C. and maintained there for 4.5 hours. The copolymer is isolated, characterized, and tested for absorption. The results are reported in Table 1.

TABLE 1

CHARACTERIZATION AND ABSORPTION OF COATING COPOLYMERS

Example No.	1	2	Comparative Example 1
Characterization			
Copolymer comp. caprolactone/glycolide/GA[1]	90/5/10 by mole	90/8/4 by mole	90/10/0 by wt. (90/10/0 by mole)
Intrinsic Viscosity of copolymer in HFIP. dl/g	0.19	0.31	0.28
Melting Point[2]	41–44° C.	42–40° C.	35–45° C.
Absorption			
In Vitro hydrolysis at 100° C. (sterile water) Percent nonhydrolyzed			

TABLE 1-continued

CHARACTERIZATION AND ABSORPTION OF COATING COPOLYMERS			
Example No.	1	2	Comparative Example 1
copolymer[3] at			
2 days	19.79	25.76	77.23
2 days (repeat)	15.82	35.23	81.80

[1]Glycolic acid
[2]Determined by hot stage microscopy
[3]Determined by measuring weight loss of copolymer after the indicated number of days

The data from Table 1 shows a significant increase in the rate of hydrolysis for the copolymers of this invention compared to prior art copolymers of ϵ-caprolactone and glycolide. The rate of hydrolysis is a measure of the rate of absorption since synthetic copolymers degrade via hydrolysis.

A 10 and 15 percent coating solution of each of the copolymers of Examples 1 and 2, and Comparative Example 1, in toluene is prepared. A size 2/0 (USP standard) Vicryl ® poly(lactide-co-glycolide) braided multifilament suture is coated with each coating solution using conventional laboratory coating equipment. The physical properties of the coated sutures are evaluated and the results are reported in Table 2 as Examples 3, 4, and Comparative Example 2, which correspond to Examples 1, 2, and Comparative Example 1, respectively.

TABLE 2

PHYSICAL PROPERTIES OF SUTURES COATED WITH COPOLYMERS						
	Example No.					
	3		4		Comparative Example 2	
	10% Sol. caprolactone/ glycolide/GA[1] Copolymer 90/5/10 by mole IV = 0.19 dl/g	15% Sol.	10% Sol. caprolactone/ glycolide/GA[1] copolymer 90/8/4 by mole IV = 0.31 dl/g	15% Sol.	10% Sol. caprolactone/ glycolide/GA[1] copolymer 90/10/0 by wt. (90/10/0 by mole) IV = 0.28 dl/g	15% Sol.
Dia., (mils)	12.6	12.7	12.8	12.7	12.9	12.9
Tissue Drag[2], gms	18.34	22.13	22.13	17.00	32.25	14.54
Wet Roughness Tiedown[3], gms	310.32	353.98	137.89	113.41	149.66	124.40
Percent Elong.[4]	17.7	18	16.6	17.3	17.6	17.3
Dry Knot Tensile[4], psi	73,800	72,600	73,800	69,500	71,900	68,800
Wet Knot Tensile[4], psi	75,400	71,800	73,000	71,000	71,900	70,400
Dry Str. Tensile[4], psi	124,300	121,600	116,600	119,200	112,500	113,200

[1]Glycolic acid
[2]Tissue Drag is a measure of the relative smoothness of the suture while passing through tissue, and is determined by using an Instron Tensile Tester and a recording device.
[3]Tiedown measured on a Table-Model Instron Tensile Tester as described in U.S. Pat. No. 3,942,532.
[4]Tensile properties and elongation determined generally according to the procedures outlined in U.S. Pat. No. 4,838,267. Wet tensile properties were measured after immersing the coated suture in water at 25° C. for 24 hours.

The data from Table 2 illustrates comparable physical properties achieved for sutures coated with the copolymers of this invention relative to the physical properties of sutures coated with prior art copolymers of ϵ-caprolactone and glycolide.

Similar outstanding results can be obtained by varying the mole ratio of each of the comonomer components of the copolymer. A coated suture with tailor-made properties can be prepared by selecting an appropriate multifilament suture with the desired coating copolymer.

We claim:

1. A copolymer of a predominant amount of ϵ-caprolactone and the balance glycolide and glycolic acid, at a concentration of glycolic acid such that the intrinsic viscosity of the copolymer in hexafluoroisopropyl alcohol is between about 0.15 to about 0.60 dl/g.

2. The copolymer of claim 1 wherein the amount of ϵ-caprolactone is between about 80 to about 95 mole percent.

3. The copolymer of claim 2 wherein the amount of ϵ-caprolactone is between about 90 to about 95 mole percent.

4. The copolymer of claim 3 wherein the intrinsic viscosity of the copolymer is between about 0.20 to about 0.50 dl/g.

5. The copolymer of claim 4 wherein the melting temperature of the copolymer is between about 35° to about 50° C.

6. The copolymer of claim 5 wherein the amount of glycolic acid is between about 1 to about 15 mole percent.

7. The copolymer of claim 6 wherein the amount of glycolide is between about 2 to about 10 mole percent.

8. A coating for a surgical suture comprising a solution of the copolymer of claim 1 or 7 in an organic solvent.

9. The coating of claim 8 wherein the amount of copolymer in solution is between about 1 to about 20 weight percent.

10. The coating of claim 9 wherein the suture is an absorbable monofilament or multifilament suture with or without an attached needle.

11. The coating of claim 10 wherein the suture is an absorbable multifilament suture.

12. The coating of claim 11 wherein the absorbable multifilament suture is in the form of a braid.

13. The coating of claim 12 wherein the suture is prepared from a polymer of a lactone or one or more lactones.

14. The coating of claim 13 wherein the multifilament suture is a poly(lactide-co-glycolide) braided multifilament suture.

15. An absorbable multifilament suture coated with the copolymer of claim 1.

16. An absorbable multifilament suture coated with the copolymer of claim 7.

* * * * *

EXHIBIT 11

US005312437A

United States Patent [19]

Hermes et al.

[11] Patent Number: 5,312,437

[45] Date of Patent: May 17, 1994

[54] **ABSORBABLE COATING COMPOSITION AND SUTURE COATED THEREWITH**

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[73] Assignee: **United States Surgical Corporation**, Norwalk, Conn.

[21] Appl. No.: **896,856**

[22] Filed: **Jun. 12, 1992**

[51] **Int. Cl.**[5] **A61L 17/00**

[52] **U.S. Cl.** **606/230**; 606/231; 428/375; 428/378

[58] **Field of Search** 606/230, 231; 428/275, 428/375, 378; 525/354, 408

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4,788,979	12/1988	Jarrett et al.	606/230
4,857,602	8/1989	Casey et al.	606/230
5,123,912	6/1992	Kaplan et al.	606/230

FOREIGN PATENT DOCUMENTS

0239775	10/1987	European Pat. Off.	606/77

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Gary Jackson

[57] **ABSTRACT**

An absorbable composition for application to a surgical suture to improve the knot tie-down and/or knot security characteristics thereof is obtained from the reaction of a poly(oxypropylene) glycol and a lactide/glycolide copolymer, optionally, in the presence of an initiator and/or catalyst.

36 Claims, No Drawings

ABSORBABLE COATING COMPOSITION AND SUTURE COATED THEREWITH

BACKGROUND OF THE INVENTION

This invention relates to an absorbable coating composition for surgical sutures and to a coated surgical suture exhibiting improved knot tie-down and/or knot security characteristics.

Since monofilament synthetic absorbable suture materials are generally stiffer than their catgut or collagen counterparts, multifilament, e.g., braided or twisted, constructions have been employed in many instances for greater softness and flexibility. Multifilament sutures, however, exhibit a certain degree of undesirable roughness in what is generally referred to as knot tie-down performance, i.e., the ease or difficulty of sliding a knot into place down the suture. It has therefore become a common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well. Known suture coating compositions include those described in U.S. Pat. Nos. 3,867,190; 3,942,532; 4,027,676; 4,043,344; 4,047,533; 4,080,969, 4,105,034; 4,185,637, 4,201,216; 4,470,416; 4,624,256; 4,649,020; 4,716,203, 4,788,979; and, 4,857,602.

U.S. patent application Ser. No. 07/707,437, filed May 28, 1991 describes an absorbable composition for improving the knot tie-down properties of a suture, the composition being either a copolymer derived from the copolymerization of a low molecular weight poly(oxyethylene) glycol, glycolide monomer and a lactide monomer or a copolymer derived from the copolymerization of a low molecular weight polyalkylene glycol and a preformed copolymer of lactide and glycolide.

Notwithstanding the extensive research in attempting to improve the tie-down characteristics of surgical sutures, sutures having even further improved knot tie-down properties are still desirable.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an absorbable coating composition for surgical sutures, particularly multifilament synthetic sutures.

Another object of this invention is to provide a coated surgical suture exhibiting improved knot tie-down characteristics.

Still another object of the present invention is to provide an absorbable coated synthetic suture exhibiting improved knot tie-down characteristics under both wet and dry conditions.

A further object of this invention is to provide an absorbable coated synthetic suture exhibiting improved knot security characteristics.

These and other objects are achieved herein by providing an absorbable coating composition comprising the product obtained by reacting a mixture of poly(oxypropylene) glycol and a lactide/glycolide copolymer in the presence or absence of an initiator. Coated sutures having improved knot tie-down characteristics under dry and wet conditions as well as improved knot security characteristics are provided by depositing a coating of the afore-described composition on the suture.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred poly(oxypropylene) glycols used in preparing the suture coating composition of this invention possess molecular weights ranging from about 400 to about 6,000 and more preferably from about 1,000 to about 4,000 and viscosities of from about 70 to about 2,000 cp, preferably from about 150 to about 1,200 cp and, more preferably, from about 900 to about 1200 cp. Suitable poly(oxypropylene) glycols include those of the Pluracol (BASF-Wyandotte), Voranol (Dow), Poly G (Olin), Polylite (Reichhold), Thanol (Texaco) and Niax (Union Carbide) series.

The preferred lactide/glycolide copolymers are made from about 90 to about 65 mole percent lactide, from about 10 to about 35 mole percent glycolide and from 0 to about 5 mole percent of one or more additional monomers copolymerizable therewith such as p-dioxanone, ϵ-caprolactone, etc. Copolymers of this type and their preparation are known, e.g., from U.S. Pat. Nos. 2,668,162; 2,703,316; 3,297,033; 3,620,218; 3,636,956; 3,736,646; 3,773,919,; 3,797,499; 3,839,297; 3,867,190; 3,982,543; 4,273,920; and, 4,523,591.

More preferred lactide/glycolide copolymers for use in preparing the coating composition herein are the 85–70 mole percent lactide/15–30 mole percent glycolide copolymers described in U.S. Pat. No. 4,523,591, the contents of which are incorporated by reference herein. The copolymers are advantageously prepared with L-lactide and possess a glass transition temperature of at least about 54° C. when measured by differential scanning calorimetry at 20° C./min and an inherent viscosity of at least about 0.9 when measured in chloroform at a concentration of 0.25 g/dl. A particularly preferred lactide/glycolide copolymer is prepared with about 18 mole percent lactide and about 82 mole percent glycolide.

The absorbable coating composition herein is prepared by reacting the poly(oxypropylene) glycol(s) with the lactide/glycolide copolymer(s), generally in the presence of an esterification catalyst such as stannous chloride, stannous octoate, etc., and, optionally, an initiator. Suitable initiators include glycols such as ethylene glycol, propylene glycol, diethylene glycol and dipropylene glycol. A preferred glycol, diethylene glycol, is advantageously employed at a level of from about 0.01 to about 0.1 weight percent, and preferably at a level of from about 0.02 to about 0.5 weight percent, of the reaction medium. The weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer can vary from about 4:1 to about 1:4 and preferably from about 2:1 to about 1:2, respectively. Typically, the reaction is carried out in an inert atmosphere, e.g., nitrogen, at temperatures, for example, of from about 125° to about 200° C., and preferably from about 150° to about 160° C. When employing a lactide/glycolide copolymer possessing an inherent viscosity of at least about 0.9, it is preferred to carry out the reaction until the inherent viscosity of the coating composition has fallen below about 0.9, and more preferably below about 0.5, when measured in chloroform at a concentration of 0.25 g/dl. Reaction periods of from about 10 to about 24 hours are generally sufficient to accomplish this.

The absorbable coating composition of the present invention is non-toxic and physiologically inert. It can be applied to the surface of a suture in the form of a solution and/or dispersion in a volatile carrier such as

methylene chloride or acetone. Solidification of the coating on the suture surface occurs upon evaporation of the carrier.

The coating composition can be applied to a suture by any suitable process, e.g., passing the suture through a solution of the coating composition, past a brush or other coating solution applicator, or past one or more spray nozzles dispensing the coating solution. The suture wetted with the coating solution is subsequently passed through or held in a drying oven for a time and at a temperature sufficient to volatilize and drive off the solvent.

The coating composition can, if desired, contain one or more other components, e.g., dyes, antibiotics, antiseptics, growth factors, anesthetics, anti-inflammatory agents, etc.

While the coating composition herein can be applied to any type of suture, it is essentially intended for application to a braided suture, a preferred type of which is disclosed in U.S. Pat. No. 5,019,093, the contents of which are incorporated by reference herein. The amount of coating composition applied to a braided suture will vary depending upon the structure of the suture, e.g., the number of filaments, tightness of braid or twist, the size of the suture and its composition.

The coating composition herein can be used for both "unfilled" as well as "filled" sutures, the latter designating braided bioabsorbable sutures containing a storage stabilizing material as disclosed in U.S. Pat. Nos. 5,037,429 or 5,051,272, the contents of which are incorporated by reference herein. For an "unfilled" suture, the coating composition can be applied at a level of from about 0.5 to about 4 weight percent or more and preferably from about 1 to about 3 weight percent. Advantageously, the coating composition is applied to the suture prior to application of the storage stabilizing material. For a filled suture, the amount of applied coating composition can range from about 0.2 to as much as about 3 weight percent or more and preferably from about 0.5 to about 2 weight percent. As a practical matter, it is generally preferred to apply the minimum amount of coating composition consistent with good tie-down performance. This level of coating add-on can be readily determined for any particular suture coating system employing routine experimental procedures.

In the case of an unfilled or filled braided suture, prior to application of the coating composition, it can be advantageous to calender the suture in order to improve the uniformity with which the coating composition is laid down upon the suture surface. A calendering operation can also be beneficial when carried out on a coated suture where the suture is to be filled with a storage stabilizing material. In this case, calendering will tend to break up the coating facilitating penetration of the interior spaces of the suture by the storage stabilizing material.

A preferred method for calendering a braided suture and an apparatus for carrying out the method are disclosed in copending U.S. patent application Ser. No. 07/652,939, filed Feb. 8, 1991, the contents of which are incorporated by reference herein. In accordance with Ser. No. 07/652,939, calendering of a braided suture is achieved by applying a compressive force to the suture in a first line or direction generally transverse to the longitudinal direction of the suture, the compressive force being of sufficient magnitude as to flatten the suture in a direction orthogonal to the direction in which the compressive force is applied. Preferably, a second application of compressive force is applied to the suture in a direction generally transverse to that of the first compressive force and transverse to the longitudinal direction of the suture. The second compressive force is substantially equal in magnitude to the first compressive force so that the suture returns to its original cross-sectional configuration.

The apparatus for implementing the foregoing calendering method includes at least one pair of rollers which are biased towards each other to apply a compressive force to the suture as the suture passes between them. Optionally, a second pair of rollers is provided which is oriented at an angle (preferably 90°) to the first pair of rollers and transverse to the longitudinal direction of the suture. Following passage between both the first and second pair of rollers, the suture will have been alternately compressed, or flattened, in a first direction and thereafter in a second direction at an angle to the first direction.

The following examples are illustrative of the absorbable coating composition of this invention, its preparation and sutures coated therewith.

EXAMPLE 1

This example illustrates the preparation of an absorbable suture coating composition in accordance with the invention.

A poly(oxypropylene) glycol of 4,000 average molecular weight (nominal) and a viscosity of from 900–1200 cp, 677±1 g, was introduced into a reactor equipped with a stirrer. Following a minimum 6 hour period of drying the poly(oxypropylene) glycol in a stream of anhydrous nitrogen gas, a previously dried lactide/glycolide copolymer containing 82 mole percent lactide and 18 mole percent glycolide and an inherent viscosity of at least 0.9 when measured in chloroform at a concentration of 0.25 g/dl (prepared as disclosed in U.S. Pat. No. 4,523,591 referred to above), 1,323±1 g, was introduced into the reactor. The reactor, which was maintained under a blanket of nitrogen gas, was heated to a temperature of 155°–170° C. Thereafter, 0.4±0.05 g stannous octoate catalyst and 0.4±0.05 g diethylene glycol initiator were added to the reactor, the latter being stirred at a rate of 55–60 rpm. Following a reaction period of 20–25 hours, the reaction product was recovered and residual reactant(s) removed therefrom at elevated temperature and under a pressure not exceeding 10 Torr, the temperature profile being as follows:

1. Ramped to 80° C. at 5° C./hr.
2. Soaked at 80° C. for 1 hr.
3. Ramped to 125° C. at 2.5° C./hr.
4. Soaked at 125° C. for 1–48 hrs.
5. Cooled to ≦30° C.

The reaction product, which had an inherent viscosity below 0.5 when measured in chloroform at a concentration of 0.25 g/dl, was used as the coating composition in Examples 2 and 3 which follow.

EXAMPLE 2: COMPARATIVE EXAMPLES 1–3

Suture knot security for a coated suture in accordance with this invention (Example 2) and three known types of suture (Comparative Examples 1–3) was evaluated in divided canine fascia (linea alba) using a standard surgeon's knot.

The sutures of Example 2 were size 0 synthetic absorbable braided sutures constructed in accordance with U.S. Pat. No. 5,019,093, and coated with approxi-

mately 2.6 percent by weight of suture with the coating composition of Example 1 using the apparatus of Ser. No. 07/652,929, supra, by passing the suture through calender rolls, past a coating head to deposit the desired amount of coating composition in solvent and evaporating the solvent in a drying oven. Thereafter, the coated suture was calendered and filled with approximately 10 weight percent lycerin/calcium lactate in accordance with U.S. Pat. No. 5,037,429 using the calendering and filling apparatus of Ser. No. 07/652,939.

The sutures of Comparative Example 1 were size 0 Vicryl® synthetic absorbable braided sutures from Ethicon Inc. The sutures are believed to be coated with a copolymer of glycolide/lactide with calcium stearate.

The sutures of Comparative Example 2 were size 0 sutures constructed in accordance with U.S. Pat. No. 5,019,093, coated with approximately 1.4 percent by weight of suture with a 50:50 weight ratio copolymer of glycolide/lactide (18:82 mole percent) and poly(oxyethylene) glycol as disclosed in pending U.S. patent application Ser. No. 07/707,437, U.S. Pat. No. 5,123,912, referred to above and filled with approximately 10 weight percent glycerin/calcium lactate in accordance with U.S. Pat. No. 5,037,429. The sutures of Comparative Example 3 were coated and filled in substantially the same manner as in Example 2 employing the same equipment.

The sutures of Comparative Example 3 were the same as the sutures of Comparative Example 2 except that the coating was applied at approximately 3.0 percent by weight of suture.

The knot was configured as a hand tie (two right over left throws plus one left over right throw). The sutures were evaluated in normal abdominal fascia as well as thicker fascia toward the pubis The results of the testing are set forth below as the number of sutures which held without slipping per total number of sutures tied.

	Normal Fascia	Heavy Fascia
Example 2	4:4	4:6
Comparative Example 1	4:8	3:4
Comparative Example 2	1:3	0:2
Comparative Example 3	1:6	—

These results demonstrate the superior knot security characteristics conferred by the suture coating composition of this invention compared to that obtained with known coating compositions.

EXAMPLE 3; COMPARATIVE EXAMPLES 4–6

Knot run-down for a coated suture in accordance with this invention (Example 3) and three known types of suture (Comparative Examples 4–6) was evaluated by forming a hand tied square knot (right over left throw plus left over right throw) approximately 1 cm from the fascial edge of canine tissue and then running the knot down tightly around the fascial edge.

The sutures of Example 3 were size 3/0 sutures identical in all other respects to the sutures of Example 2 and the sutures of Comparative Examples 4, 5 and 6 were size 3/0 sutures identical in all other respects to the sutures of Comparative Examples 1, 2 and 3, respectively The results of the testing are set forth below as the number of sutures which ran down and the total number of tries.

	Knot Run Down
Example 3	4:6
Comparative Example 4	6:6
Comparative Example 5	3:6
Comparative Example 6	2:6

The test results show that sutures coated with the coating composition of the present invention demonstrate superior run-down characteristics compared to sutures of identical construction which have been coated with the composition disclosed in pending U.S. patent application Ser. No. 07/707,437, filed May 28, 1991, referred to above. Moreover, the properties of the coated suture compare favorably with those of a commercial suture of comparable size.

What is claimed is:

1. A suture coated with a coating composition comprising the product obtained by reacting a mixture of poly(oxypropylene) glycol and lactide/glycolide copolymer.

2. The suture of claim **1** wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 400 to about 6,000.

3. The suture of claim **1** wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 1,000 to about 4,000.

4. The suture of claim **1** wherein the lactide/ glycolide copolymer is prepared with L-lactide.

5. The suture of claim **1** wherein the lactide/glycolide copolymer contains from about 90 to about 65 mole percent lactide and from about 10 to about 35 mole percent glycolide.

6. The suture of claim **1** wherein the lactide/glycolide copolymer contains from about 85 to about 70 mole percent lactide and from about 15 to about 30 mole percent glycolide.

7. The suture of claim **1** wherein the lactide/glycolide copolymer prior to reaction with the poly(oxypropylene) glycol possesses a glass transition temperature of at least about 54° C. when measured by differential scanning calorimetry at 20° C./min and an inherent viscosity of at least about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

8. The suture of claim **7** wherein the composition following reaction possesses an inherent viscosity of less than about 0.9 when measured in chloroform at a concentration of 0.25 g.dl.

9. The suture of claim **7** wherein the composition following reaction possesses an inherent viscosity of less than about 0.5 when measured in chloroform at a concentration of 0.25 g/dl.

10. The suture of claim **1** wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 4:1 to about 1:4.

11. The suture of claim **1** wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 2:1 to about 1:2.

12. The suture of claim **1** wherein the composition following reaction possesses in inherent viscosity of less than about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

13. The suture of claim **1** wherein the composition following reaction possesses an inherent viscosity of less than about 0.5 when measured in chloroform at a concentration of 0.25 g/dl.

14. The suture of claim 1 wherein the poly(oxypropylene) glycol is reacted with the lactide/glycolide copolymer in the presence of an initiator.

15. The suture of claim 14 wherein the initiator is a glycol.

16. The suture of claim 15 wherein the glycol is diethylene glycol.

17. The suture of claim 1 wherein the suture is a synthetic multifilament suture.

18. The suture of claim 1 wherein the suture is an absorbable synthetic multifilament suture.

19. The suture of claim 1 exhibiting improved knot tie-down and/or knot security characteristics compared with the knot tie-down and/or knot security characteristics of the same suture coated with an equivalent amount of an absorbable composition obtained by reacting a poly(oxyethylene) glycol with a mixture of lactide and glycolide and/or lactide/glycolide copolymer.

20. A method of improving the knot tie-down and/or knot security characteristics of a suture which comprises coating the suture with an absorbable composition comprising the product obtained by reacting a mixture of poly(oxypropylene) glycol and lactide/-glycolide copolymer.

21. The method of claim 20 wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 400 to about 6,000.

22. The method of claim 20 wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 1,000 to about 4,000.

23. The method of claim 20 wherein the lactide/-glycolide copolymer is prepared with L-lactide.

24. The method of claim 20 wherein the lactide/-glycolide copolymer contains from about 90 to about 65 mole percent lactide and from about 10 to about 35 mole percent glycolide.

25. The method of claim 20 wherein the lactide/-glycolide copolymer contains from about 85 to about 70 mole percent lactide and from about 15 to about 30 mole percent glycolide.

26. The method of claim 20 wherein the lactide/-glycolide copolymer prior to reaction with the poly(oxypropylene) glycol possesses a glass transition temperature of at least about 54° C. when measured by differential scanning calorimetry at 20° C./min and an inherent viscosity of at least about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

27. The method of claim 26 wherein the composition following reaction possesses an inherent viscosity of less than about 0.9 when measured in chloroform at a concentration of 0.25 g.dl.

28. The method of claim 26 wherein the composition following reaction possesses an inherent viscosity of less than about 0.5 when measured in chloroform at a concentration of 0.25 g/dl.

29. The method of claim 20 wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 4:1 to about 1:4.

30. The method of claim 20 wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 2:1 to about 1:2.

31. The method of claim 20 wherein the poly(oxypropylene) glycol is reacted with the lactide/glycolide copolymer in the presence of an initiator.

32. The suture of claim 31 the initiator is a glycol.

33. The suture of claim 32 wherein the glycol is diethylene glycol.

34. The method of claim 20 wherein the suture is a synthetic multifilament suture.

35. The method of claim 20 wherein the suture is an absorbable synthetic multifilament suture.

36. The method of claim 20 wherein the resulting coated suture exhibits improved knot tie-down and/or knot security characteristics compared with the knot tie-down and/or knot security characteristics of the same suture coated with an equivalent amount of an absorbable composition obtained by reacting a poly(oxyethylene) glycol with a mixture of lactide and glycolide and/or lactide/glycolide copolymer.

* * * * *

EXHIBIT 12

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

COPY

DePUY MITEK, INC.,
Plaintiffs,

vs.

ARTHREX, INC., a Delaware corporation,
Defendants.

DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Courtyard Marriott, 423 Speen Street, Natick, Massachusetts, on Thursday, 26 January, 2006, commencing at 10:44 a.m.

Ethicon had multiple development programs going, some of which were to make a product that were -- had better properties than silk, and silk has really good handling properties. Some of them had to do with higher strength sutures. Some of them had to do with different biologic profiles in terms of strength retention over time. And the initial discussions were how can we address those types of problems with a combination of fiber types.

So, the initial conversations -- and one of the avenues that came out of that was this maybe opportunity to have a suture that has strength better than silk, but pliability like silk. So, that was one of them.

Q. Okay.

A. And that was one that Al and Art had considered in the past. Again, I'm not clear how far they took that in the past, but they at least considered that. And that was one that we elected to pursue earlier than later, because we had the materials, essentially. We thought it was good opportunity.

Q. So, if I understand your testimony -- at least at the very beginning stage you wanted something that was stronger than silk but handled

as well as silk, is that --

A. That was certainly one of the embodiments we were going after.

Q. As the -- as the project -- as the project progressed and as you applied for a patent, is it correct that you were trying to get something that handled better than a homogenous braid but didn't lose strength -- appreciably lose strength from the conventional homogenous braid?

A. The overall project, yeah, I think that was -- that would be a fair assessment of the objective of the overall project.

Q. All right. And the conventional homogenous braid that you were talking about that you wanted to not lose appreciative strength then was Ethibond, is that correct?

A. Right. Ethibond -- well, Ethibond, you know, had good strength, but maybe not as good handling properties as silk,.

Q. Right.

A. Silk had lower strength, good handle properties, and again, one of the concepts was we -- maybe we could get the best of both.

Q. All right. But as you applied for the 446 patent, was it the object there to have something

interest in how do you improve the knot strength of them, and can you -- that was -- that was something we discussed.

Q. I'm not sure I understand your answer.

A. Go ahead.

Q. And I'm trying to --

A. Sure.

Q. When you had this idea that you could blend Dyneema together with PET, were you -- did you believe it would make an acceptable suture or an unacceptable suture?

A. No. We believed -- we believed that that could offer a suture with straight tensile that was better than Ethibond, and you know, could potentially solve the knot issues, and again, that was a generic view for all of the high-tenacity fibers.

Q. You thought it was a good idea --

A. Yes. Yes.

Q. -- rather than a bad idea?

A. No, we viewed -- we viewed that as a potential good idea.

Q. And you didn't think, Oh, that's a bad idea.

MR. BONELLA: Objection. Asked and

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS
DAY II

COPY

DePUY MITEK, INC.,
Plaintiffs,

vs.

ARTHREX, INC., a Delaware corporation,
Defendants.

CONTINUED DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Hilton Hotel, 25 Allied Drive, Dedham, Massachusetts, on Friday, 3 February, 2006, commencing at 9:06 a.m.

Q. Were the braids -- was a tipping put on the braids?

A. There would not be tipping, since we never intended to attach needles to this evaluation.

Q. Were the braids sterilized?

A. Typically at this level -- the answer is, I believe, no. At this point in an evaluation, we would typically evaluate presterile properties.

Q. Okay. Could you turn to Page 2638. So, the fourth page of the --

A. Yes.

Q. -- fourth page of this -- the entry. Under "Discussion," the first sentence says, "From a braid processing viewpoint, the commingled yarn was the least problematic braid, followed by the yarn blend. The carrier blend presented the most difficulties in core popping and braid looseness."

What did you mean by "The carrier blends presented the most difficulties in core popping and braid looseness"?

A. Core popping is a common braid defect. You know, any braid text would -- would cover it. The ability to adjust the tension on the yarn that affects core popping was more difficult with the carrier blend and the yarn blend than the

Q. Could you read her note for the record, please.

A. Yes. "Being reviewed as potential new product for Ethicon. May offer significant advantages if technical problems of mixing of materials with dissimilar stress/strain properties can be overcome."

Q. Okay. Do you have an understanding of what was meant by "-- if technical problems of mixing of materials with dissimilar stress/strain properties can be overcome"?

A. I believe she's referring to the tension issues on processing the heterogeneous yarns.

Q. That we've discussed last week and earlier today?

A. That would be my understanding.

Q. All right. And is it your understanding that those --

A. Although this is Barbara's words, not mine.

Q. That's what I'm trying to under -- to get your understanding.

A. Yeah.

Q. And is it your understanding that those technical problems with tension had not yet been

overcome as of February 8th, 1990?

MR. BONELLA: Object to the form.

A. I don't know if -- if Barbara at the director level or manager level would have had firsthand knowledge of that, so --

THE WITNESS: I'm sorry. Could you repeat the question.

(Question read back.)

A. Once again, I think we're in the realm of manufacturing requirements versus proof of concept requirements in terms of have the technical problems been overcome?

Q. Well, was it your understanding that -- well, do you understand -- do you know the basis of Ms. Schwartz's comment, what that was based upon -- what her comment was based upon?

A. No, I'm inferring it from -- from the comments and from what we've read.

Q. Okay. So, do you have an understanding one way or another exactly what she was talking -- well, strike that.

MR. SABER: Why don't we take our break.

(Recess was taken.)

Q. Doctor Steckel, there came a time, of course, when Ethicon applied for the 446 patent, of

A. To the amount of surface area in the multifilament braid and the potential for -- let's just leave it at that: The amount of surface area between a multifilament versus a monofilament.

Q. Does it have to do with the roughness of the braid versus smoothness of the braid?

A. Less to do with that, more to do with the fact that the multifilament braid has interstices (sp) that, you know, could potentially harbor bacteria, etcetera.

Q. Going back to this paragraph that begins at Line 26, it then goes on to speak about, "For example, multifilament sutures almost universally possess a surface coat to improve handling properties." Is improving handling properties one of the specific properties of multifilament braids that is -- that coating -- that this paragraph is saying coating is designed to improve?

MR. BONELLA: Object to form.

A. I'm sorry.

Q. Let me rephrase that. That was --

A. Yeah. I'm sorry.

Q. It says, "For example, multifilament sutures almost universally possess a surface coating to improve handling properties." Do you

see that?

A. Yes.

Q. What's your understanding of what handling properties are being referred to in that sentence?

A. My understanding, because the surface coating would be for knot handling, knot tie-down handling properties.

Q. Knot tie-down?

A. Knot tie-down.

Q. Anything else?

A. Not to my understanding.

Q. How about how well the knot slides, is that one of the things that --

A. Oh, yeah. That's part of knot tie-down.

Q. Why don't you explain to me what is part of knot tie-down.

A. Okay. Yeah. I mean, knot tie-down refers to the properties of a suture during the tying process, which would include the force, smoothness, roughness when one arm of the suture is being pulled against the second arm of the suture.

Q. How about is -- is coating designed to help the -- the suture go through tissue more easily?

MR. BONELLA: Objection. Calls for expert

EXHIBIT 13

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. No. 04-12457 PBS

- - -

ORIGINAL

DePUY MITEK, INC.,
a Massachusetts corporation,

Plaintiff,

v.

ARTHREX, INC.,
a Delaware corporation,

Defendant.

- - -

WEDNESDAY NOVEMBER 30, 2005

- - -

Oral deposition of DENNIS D. JAMIOLKOWSKI, taken pursuant to Notice, before Jeanne Cahill, RMR, CRR, at the offices of Woodcock Washburn, LLP, One Liberty Place, 33th Floor, 1650 Market Street, Philadelphia, Pennsylvania, commencing at 9:10 a.m.

last sentence in that paragraph that starts "the composite also ranked"?

A. Okay. What I would like to do is not miss that second sentence.

Q. That's fine.

A. I'm going to read the whole thing. "the intrinsic tensile and knot strengths were 87,000 pounds per square inch and 48,000 pounds per square inch, respectively. The composite also ranked better" -- oh, "than" -- I can't quite make out that word, but then the following --

Q. Is it "silk"?

A. Yes, "better than silk and ethabond in knot tie-down, even without a coating." I don't know what the word is between "then" and "silk."

Q. What is knot tie-down?

A. Beautiful. This description that I had been providing of a surgeon taking the two ends of the suture, putting one inside the other, and now pulling the ends, and sliding that throw down, is knot tie-down. It's the -- it's part of the process of constructing a knot. And again, they will very often have to start these throws well away from the tissue. And knot tie-down -- a good knot tie-down result would be one in which this process is very smooth, with a lack of chatter.

Q. And that's one of the improved handling properties that we were discussing?

A. Yes, sir.

Q. You said at the end of the sentence, it says "even without a coating"?

A. Yes.

Q. Does that indicate to you that the composite we're -- the composite we're talking about, I take it, is still the PET/PTFE?

A. Correct.

Q. That that was uncoated, that composite?

A. It certainly sounds that way.

Q. Do you know whether there were any tests done with the composite being coated?

A. There may very well have. I'm not aware of any.

Q. Do you know why it was reported that knot tie-down was better, and they added the words, "even without a coating"?

A. Because knot tie-down is an important suture characteristic. With the discovery that the knot tie-down performance was particularly good, I believe that the author wanted to have that recorded.

Q. Why did he make the reference, "even without a coating"?

A. Because sutures are very frequently coated. In particular, braids are very often coated.

Q. Why is that?

A. Because a braid surface is not very smooth, generally, and consequently, tends to chatter much more than would a monofilament upon knot tie-down. So what the industry has done is that these suture materials that are multifilament in nature, that is, braids, would generally be coated. Not always, but generally.

Q. And why?

A. So as to be able to provide better knot tie-down characteristics. Again, lack of chatter, smoothness during tie-down.

Q. Was it considered an advantage of this suture that you could achieve better knot tie-down than ethabond and silk even without a coating on the composite?

A. On reading this statement, the author certainly felt that way, it appears.

Q. Does Ethicon feel that way?

A. I would think that it depends on who you talk to at Ethicon, because the advantage of not providing a coating might be economic, but if that is the only characteristic in which it's an advantage, that may not necessarily be the basis of putting a new suture material out.

EXHIBIT 14

DISK ENCLOSED

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

C.A. No. 04-12457 PBS

* * * * * * * * * * * * * *

ORIGINAL

DePUY MITEK, INC.,

Plaintiff *

v. *

ARTHREX, INC., a Delaware *

corporation, *

Defendant *

* * * * * * * * * * * * * *

VOLUME I

PAGES 1-245

DEPOSITION OF DePUY MITEK, INC. by SHELBY COOK KORNBLUTH, a witness called on behalf of the Defendant, pursuant to the Federal Rules of Civil Procedure, before Jessica L. Williamson, Registered Merit Reporter, Certified Realtime Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Hilton Hotel, 25 Allied Drive, Dedham, Massachusetts, on Tuesday, November 15, 2005, commencing at 9:01 a.m.

Q. And which one did you choose?
A. The copolymer of caprolactone and glycolide.
Q. And is that called NVC?
A. Yes.
Q. Did Ethicon in making these recommendations describe to you the differences between those two coatings?
A. I don't recall.
Q. Did you have any discussions with Ethicon as to why there would be a coating?
A. No.
Q. Well, why is there a coating on -- there is a coating on the Orthocord?
A. Yes.
Q. Why is there a coating on the product?
A. To help with knot sliding.
Q. What do you mean when you say "To help with knot sliding"?
A. To help the knot slide down into the joint so that it cinches tightly. It -- you want the knot to travel down the suture.
Q. Okay.
A. And it helps with that traveling down the suture.
Q. What do you mean when you say "it helps with

A. Correct.
Q. -- of the whole concentrate?
A. Correct.
Q. Okay. And then what actually sticks is the .07 to the .15 percent, and that's the vol -- that's measured as a percentage of the volume of the suture?
A. Yes.
Q. And is that range, the .07 to .15, the same for the violet and blue?
A. Yes.
Q. Are there any other components of the Orthocord -- we've mentioned the ultra high molecular weight PE, the PDS, the two fibers, the coating. I think you mentioned the dye earlier --
A. Uh-huh.
Q. -- right? One's a blue dye, one's a violet dye. Anything else?
A. The suture is -- has a tip at each end.
Q. And what is the tip made of?
A. God, it's a combination of four different materials. They escape me right now.
Q. Okay. What is the purpose of tipping the suture?

A. The original intent of tipping the suture is so that you can -- that the end of the suture is stiff enough to insert into a needle to attach or for a surgeon to put through a free needle so that they can use a suture without a needle on it.

Q. So it's stiff enough to put it on the needle? Is that part of the manufacturing process, the first thing you described --

A. Yeah.

Q. -- what Ethicon or one of these other companies does?

A. When they attached the suture to the needle --

Q. Yes.

A. -- if you don't have a tip on there, you can't get it into the needle hole.

Q. Right. So that's part of the manufacturing process? That's the first purpose --

A. Yes.

Q. -- of tipping?

And the second purpose has to do with the surgeon?

A. Yeah, over -- I mean, over the years suture companies have added a tip to the tips of

A. -- I can't remember. Lupine has Panacryl. I can't remember the others. I think Spiralok -- I can't say.

Q. What is Ethibond?

A. Polyester suture.

Q. And all polyester?

A. Yes.

Q. Does it have a coating?

A. Yes.

Q. And do you know what coating it has?

A. Polybutylate.

Q. And who makes it?

A. Ethicon.

Q. All right. And what is Panacryl?

A. Panacryl is a copolymer of glycolide. It's PGA and PLA, so polyglycolic acid and polylactic acid.

Q. Are either one of those a polyester?

A. I can't remember. I'll have to look at the chemical composition.

Q. Why is Panacryl used for some of the products?

A. Because it's an absorbable suture.

Q. And Ethibond is not?

A. Correct.

Q. Ethibond is not considered a high-strength suture?

A. No.

Q. Panacryl's not considered a high-strength suture?

A. No.

Q. Okay. Who was the first company to sell a high-strength suture?

MR. FALKE: Objection, outside the scope of the notice. You can answer if you know.

A. I believe it was Arthrex.

Q. And that was the Fiberwire product?

A. Yes.

Q. Isn't it correct that DePuy Mitek wanted to develop a high-strength suture to compete with Fiberwire?

MR. FALKE: Objection, outside the scope of the notice.

A. Yes.

Q. Is it also true that DePuy Mitek considered that they were losing their competitive edge in the marketplace if they did not develop a high-strength suture?

MR. FALKE: Objection, outside the

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

* * * * * * * * * * * * * * *

DePUY MITEK, INC.,
Plaintiff
v.
ARTHREX, INC., a Delaware corporation,
Defendant

* * * * * * * * * * * * * * *

ORIGINAL

CONFIDENTIAL

VOLUME I
PAGES 1-197

DEPOSITION OF GARY B. McALISTER, a witness called on behalf of the Defendant, pursuant to the Federal Rules of Civil Procedure, before Jessica L. Williamson, Registered Merit Reporter, Certified Realtime Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Four Points Sheraton, 1125 Boston Providence Turnpike, Norwood, Massachusetts, on Thursday, December 22, 2005, commencing at 8:59 a.m.

A. I've read plastics books so that I'm aware of it.

Q. What plastics books?

A. Plastic reference books. I don't recall the title.

MR. FALKE: Chuck, we've been going about an hour. Do you want to take a break?

MR. SABER: Sure, any time you want.

(Recess taken.)

Q. We were talking about materials -- your information on the materials in sutures, and we were talking about Orthocord. Is Orthocord a coated product?

A. Yes.

Q. Okay. Do you know what coating is on that?

A. No.

Q. Do you know why there's a coating on the product?

A. Yes.

Q. Okay. Why is there a coating on the product?

A. It makes the handling much better, is my understanding that that's why coatings are put on there. It'll tie better, it'll slide

better. They call it the hand, it improves the hand of the suture. Can I put my jacket on? It's cold in here.

Q. That's absolutely fine.

MR. FALKE: Why don't we go off the record for one second.

(Discussion off the record.)

MR. SABER: Could you read back his last answer?

(Record read.)

Q. What do you mean, "they call it the hand"?

A. That's the way -- that's the term that's been described to me as a term that relates to the handling and how it feels in the hands of a surgeon. I think that's what it refers to.

Q. Anything else for purposes of coating, why it's coated?

A. Ethicon just released a coating -- a suture that has antimicrobials embedded in the coating, so it could be a carrier for antimicrobials.

Q. Okay. Anything else?

A. No.

Q. Does coating have any role, from your

EXHIBIT 16

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. No. 04-12457 PBS

----------x

DePUY MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

v.

ARTHREX INC.,

A Delaware Corporation,

Defendants.

----------x

ORIGINAL

CONFIDENTIAL

* * *CONFIDENTIAL* * *

DEPOSITION OF ILYA KOYFMAN

Somerset, New Jersey

February 22, 2006

Reported by:

MARY F. BOWMAN, RPR, CRR

JOB NO.: SE232

KOYFMAN - Confidential

A. Yes.

Q. Did you prepare this document?

A. Yes.

Q. What is it?

A. It's a product development strategy for Orthocord.

Q. Can you turn to page DMI 082160.

A. OK.

Q. I want to ask you a little bit about the -- what comes under the heading "braiding through coating," et cetera. Particularly the last paragraph on the page. The sentence that says, "Coating selection depends on maintaining a fine balance between suture tie-down and knot security."

A. Um-hm.

Q. What did you mean by that sentence?

A. The prime reason for applying coating is to have a good tie-down, good tie-down and tissue passage and so forth. When you apply coating, you might affect other properties. So that's what I meant, you have to have a balance.

Q. The other properties being knot security?

core. You have an internal core and then you have a sheath which is braided sheath, right? So if you have a suture which -- you cut the suture length and you tip it, the tipping is a relatively rigid polymeric substance which allows for insertion of a suture into the needle. So you need this tip. So if you have a tip on both ends like in the case with Orthocord, you basically anchor two ends.

So if you have sheath too mobile, you know, you can displace some of that amount of sheath over the core and you can -- and you can accumulate it in one part. That's -- that has to be -- the amount of how much you can accumulate or the relationship to the initial diameter has to be specified.

This phenomena is called bunching, so basically you bunch up, bunch it.

Q. A part of the suture at one end?

A. Yes.

Q. That is a characteristic you are trying to avoid, bunching?

A. You try to minimize it.

Q. Why do you try to minimize bunching?

EXHIBIT 17

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

DePUY-MITEK, INC.,
A Massachusetts Corporation,
Plaintiff,
vs.
ARTHREX, INC.,
A Delaware Corporation,
Defendants.

ORIGINAL

CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

DAY 1 OF 2

DEPOSITION OF DR. DAVID S. BROOKSTEIN

Philadelphia, Pennsylvania

July 26, 2006

Reported by:

PAMELA HARRISON, RMR, CRR, CSR

of the question. 08:59:18a

THE WITNESS: I have no -- 08:59:19a

BY MR. SABER: 08:59:20a

Q. Is it PET? **08:59:20a**

A. PET and polyester are used 08:59:21a

interchangeably, yes. The polyethylene 08:59:23a

terepthlate is the official chemical name for 08:59:28a

polyester. Polyester is essentially a shorthand 08:59:32a

way of referring to polyethylene terepthlate. 08:59:36a

Q. Okay. **08:59:40a**

A. Whenever you see those terms, they're 08:59:41a

the same thing. 08:59:42a

Q. Polyester, or...? **08:59:43a**

A. Polyester and polyethylene 08:59:43a

terepthlate, T-E-R-E-P-T-H-L-A-T-E, and polyester 08:59:51a

are used interchangeably, in the literature, in 09:00:00a

the science, in teaching, by everybody. 09:00:03a

Q. Okay. And poly -- I have a little **09:00:09a**

trouble with this -- **09:00:12a**

A. Okay. 09:00:15a

Q. -- polyethylene terepthlate -- **09:00:15a**

A. Terepthlate. 09:00:16a

Q. -- is referred to as PET? **09:00:16a**

A. That is correct. 09:00:17a

Q. The -- could you -- I just want to tie **09:00:19a**

about sutures, but actually designing and developing and the quality associated with that was for U.S. Surgical; I don't recall if we coated or not. 11:16:23a 11:16:25a 11:16:32a 11:16:34a

Q. You just don't remember from that project? **11:16:35a 11:16:38a**

A. Right. 11:16:38a

Q. Do you recall whether you've had any experience with respect to coating of sutures in your background prior to your work on this case? **11:16:38a 11:16:40a 11:16:44a**

A. I don't recall, because, you know, we looked at the vascular prosthesis patent that had sutures on it, I don't recall if they were coated or not. I don't know. 11:16:49a 11:16:51a 11:16:53a 11:16:56a

Q. Have you -- do you recall whether you have had any experience with respect to what coating -- how coating impacts on suture properties? **11:16:58a 11:17:01a 11:17:08a 11:17:11a**

A. Well, I've looked at the Gitis report and tried to -- 11:17:15a 11:17:19a

Q. I'm sorry, prior to your work in this case. **11:17:20a 11:17:21a**

A. Not prior to the work in this case. 11:17:22a

Q. Okay. The -- would it be correct to say that what you've learned about coating and **11:17:23a 11:17:31a**

1	**its impact on suture properties is in conjunction**	**11:17:33a**
2	**with your work on this case?**	**11:17:35a**
3	A. That would be proper to say that, yes.	11:17:38a
4	**Q. The -- do you have an opinion as to**	**11:17:44a**
5	**whether it is generally well-known in the suture**	**11:17:45a**
6	**art that coating multifilament suture improves**	**11:17:48a**
7	**the tactile smoothless -- smoothness, pliability,**	**11:17:53a**
8	**and knot tie-down performance of that suture?**	**11:17:58a**
9	A. That's a long question. Do that --	11:18:02a
10	let's do that slower and --	11:18:05a
11	**Q. Sure, I'll even try to take it into**	**11:18:06a**
12	**parts.**	**11:18:09a**
13	A. Yeah.	11:18:09a
14	**Q. Do you have an opinion -- well, let me**	**11:18:09a**
15	**ask you this. Is it correct that it is generally**	**11:18:12a**
16	**known in the suture art that coating a**	**11:18:14a**
17	**multifilament suture improves the tactile**	**11:18:16a**
18	**smoothness of the suture?**	**11:18:18a**
19	MR. BONELLA: Objection; incomplete	11:18:22a
20	hypothetical.	11:18:23a
21	THE WITNESS: I haven't seen	11:18:24a
22	anything that says that.	11:18:25a
23	BY MR. SABER:	11:18:26a
24	**Q. You don't have an opinion one way or**	**11:18:26a**
25	**the other?**	**11:18:28a**

A. I have no opinion on that. 11:18:28a

Q. Do you know whether it is generally known in the suture art that coating a multifilament suture improves the pliability of that suture? 11:18:29a 11:18:31a 11:18:35a 11:18:39a

MR. BONELLA: Objection; incomplete hypothetical. 11:18:40a 11:18:41a

THE WITNESS: Yeah, I've seen nothing like that. I can't judge that. 11:18:42a 11:18:43a

BY MR. SABER: 11:18:45a

Q. You have no opinion one way or the other? 11:18:45a 11:18:47a

A. I have an opinion that coating only affects in a minor way the handleability. 11:18:47a 11:18:49a

Q. Okay. 11:18:52a

A. That's it. 11:18:52a

Q. Okay. Well, let me -- what do you mean when you say handleability? 11:18:52a 11:18:55a

A. You know, if the guy does this (indicating) and says it feels smooth, then that's all. And even that from what I've read in some of your experts' reports, like Burks', even that is almost imperceptible. 11:18:56a 11:18:58a 11:19:00a 11:19:06a 11:19:09a

Q. Is it -- do you agree that it is generally known in the suture art that coating a 11:19:16a 11:19:20a

1	**multifilament suture improves the knot tie-down**	**11:19:22a**
2	**performance of that suture?**	**11:19:25a**
3	MR. BONELLA: Objection; incomplete	11:19:27a
4	hypothetical.	11:19:29a
5	THE WITNESS: I've seen no	11:19:29a
6	evidence where that's discussed.	11:19:31a
7	BY MR. SABER:	11:19:33a
8	**Q. So you don't have an opinion one way**	**11:19:33a**
9	**or the other?**	**11:19:37a**
10	MR. BONELLA: Objection;	11:19:37a
11	incomplete --	11:19:38a
12	BY MR. SABER:	11:19:39a
13	**Q. Is that correct?**	**11:19:39a**
14	MR. BONELLA: Incomplete	11:19:40a
15	hypothetical on that previous question.	11:19:41a
16	THE WITNESS: My opinion is	11:19:43a
17	that coating only has an immaterial effect that	11:19:43a
18	might -- might -- affect handleability, and	11:19:47a
19	that's all.	11:19:51a
20	BY MR. SABER:	11:19:51a
21	**Q. What is that opinion based on?**	**11:19:51a**
22	A. It's based mostly on some of the work	11:19:53a
23	I've read from Gitis. It's an opinion of looking	11:19:55a
24	at the micrographs that I took and seeing the	11:19:59a
25	level of coating that was on those sutures. It's	11:20:02a

a -- it's based on some theoretical calculations I made associated with bending rigidity. It's understanding how tensile properties of fibers relate to the tensile properties of the braided structure. In no case can you show that coating does anything of any material. It's almost an afterthought to put it on. 11:20:06a 11:20:12a 11:20:17a 11:20:21a 11:20:24a 11:20:27a 11:20:31a

I think the patent even says, you know, in some cases it's expensive, don't even bother with it, it's not that a big deal. It's expensive and don't even put it on it. 11:20:45a 11:20:46a 11:20:51a 11:20:54a

Q. Just give me a moment. **11:20:57a**

A. I just want to read from the patent. 11:21:09a

MR. BONELLA: Why don't you wait until there's a question. 11:21:12a 11:21:13a

THE WITNESS: Okay. Okay. Okay. 11:21:14a

MR. BONELLA: There's no question. 11:21:15a

(Whereupon a document was marked, for identification purposes, as Defendant's Exhibit-202.) 11:21:32a 11:21:32a 11:21:33a

THE VIDEOGRAPHER: Going off the video record. 11:21:54a 11:21:55a

(A discussion was held off the record from 11:21 AM to 11:22 AM, with the video record then resuming.) 11:22:15a 11:22:15a 11:22:20a

from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. That is what I've been asked to assume. That is what my opinions are based on, those basic and novel characteristics. 12:02:23p 12:02:28p 12:02:31p 12:02:31p 12:02:33p 12:02:36p

Q. In your opinion, sir, if the coating improves one of the properties that one of the materials contributes to the braid, can it have a -- can it materially affect the basic and novel characteristics of the invention? **12:02:38p 12:02:40p 12:02:42p 12:02:45p 12:02:48p**

A. Not under this definition, no. 12:02:50p

Q. Your answer is no? **12:02:51p**

A. The answer is no. 12:02:52p

Q. Okay. **12:02:55p**

MR. SABER: Mike, this is probably a pretty good time. 12:02:55p 12:02:56p

MR. BONELLA: Okay. 12:03:00p

BY MR. SABER: 12:03:00p

Q. What's the basis for that opinion? **12:03:00p**

A. The basis for what opinion? 12:03:01p

Q. What you just said, that even if it improves the property that one of the yarns adds, it cannot affect the basic and novel characteristics. **12:03:02p 12:03:05p 12:03:10p 12:03:12p**

1	**equivalents?**	**02:29:00p**
2	A. Okay. Let me -- let me go through my	02:29:05p
3	report.	02:29:07p
4	First we look at each -- you make	02:29:07p
5	a table and we look at each claim or claim	02:29:10p
6	element and we see what that claim element or	02:29:13p
7	claim is claiming.	02:29:17p
8	Then we look under the function	02:29:18p
9	of the claim limitation. Okay? We see what it	02:29:21p
10	-- what is it -- what is the function of this, we	02:29:25p
11	make a determination what the function is, and	02:29:26p
12	then we compare it to what the function is of the	02:29:28p
13	material that's in question and we match the	02:29:31p
14	functions. Okay?	02:29:33p
15	Then we see -- once we've	02:29:34p
16	determined what the function is, we see the way	02:29:37p
17	that it met that function. And after that, we	02:29:40p
18	see what the final results are.	02:29:43p
19	So we're always -- we take the	02:29:43p
20	claim. Okay? We decide what the function,	02:29:45p
21	way or result is that we're trying to achieve,	02:29:49p
22	and then we look at the material in question	02:29:51p
23	and see if it meets the function, way and	02:29:53p
24	result for it to be an insubstantial	02:29:56p
25	difference.	02:29:58p

yarn from the second set. 02:33:10p

A. Right. 02:33:13p

Q. Correct? 02:33:13p

A. Right. 02:33:14p

Q. Now, was that your opinion or was that the function -- was that function given to you by the attorneys? 02:33:14p 02:33:16p 02:33:19p

A. No, it was the function that I got from the '446 patent. It says, My opinion regarding the function of the first fiber material is supported by the '446. 02:33:19p 02:33:21p 02:33:25p 02:33:27p

Q. No -- 02:33:29p

A. Let me -- 02:33:30p

Q. I just want you to answer my question. I mean, was this -- I'm just trying to find out does this -- are you the one who came up with the function, or was that something that was an assumption that was given to you by the attorneys? 02:33:31p 02:33:33p 02:33:36p 02:33:39p 02:33:40p 02:33:43p

MR. BONELLA: Objection. Asked and answered. 02:33:43p 02:33:44p

BY MR. SABER: 02:33:44p

Q. That's my question. 02:33:44p

A. Mr. Falke explained to me how the function/way result works from a legal 02:33:47p 02:33:50p

1	**Q. The first thing you say is Column 2,**	**02:40:06p**
2	**Lines 50 to 52, in the patent?**	**02:40:08p**
3	A. Yes.	02:40:11p
4	**Q. And this is Exhibit D?**	**02:40:11p**
5	A. Yes, sir.	02:40:14p
6	**Q. And that's the sentence that begins,**	**02:40:14p**
7	**Surprisingly --**	**02:40:16p**
8	A. Yes.	02:40:17p
9	**Q. -- the heterogeneous braids may**	**02:40:17p**
10	**exhibit -- well, tell me specifically what in**	**02:40:19p**
11	**that, because I know the numbers get a little bit**	**02:40:22p**
12	**off, as we know.**	**02:40:24p**
13	A. I understand.	02:40:25p
14	**Q. Tell me specifically what you're**	**02:40:26p**
15	**referring to at Column 2, Lines 50 to 52.**	**02:40:27p**
16	A. Well, I also have it in my -- in my	02:40:31p
17	report, the -- I quoted, The patent explains that	02:40:35p
18	the first fiber-forming material is dissimilar to	02:40:38p
19	the second set -- second fiber, and the braid of	02:40:41p
20	the similar yarns provides, quote, from the	02:40:46p
21	patent outstanding properties attributable to the	02:40:49p
22	specific properties of the dissimilar	02:40:52p
23	fiber-forming materials which make up the braided	02:40:55p
24	yarns.	02:40:57p
25	**Q. Yeah, I want -- I just want to know**	**02:41:00p**

never looked at it. 02:44:16p

Q. Okay. Did you -- do you have any understanding of what the claims of the '446 patent were as the patent application was originally filed? 02:44:16p 02:44:19p 02:44:21p 02:44:26p

A. No. 02:44:27p

Q. Have you studied as to whether there were any amendments to the claims -- 02:44:28p 02:44:31p

A. No. 02:44:33p

Q. -- in the prosecution history? 02:44:33p

A. No. 02:44:35p

Q. Okay. Do you think that understanding the prosecution history in any amendments to the claims is important for understanding the function of limitation A? 02:44:35p 02:44:39p 02:44:43p 02:44:46p

A. Not in an infringement situation, no. 02:44:53p

Q. Okay. You would agree with me that limitation A that we're discussing requires that the material be one of the specified listed materials to literally meet that limitation, correct? 02:44:59p 02:45:06p 02:45:12p 02:45:16p 02:45:20p

A. To literally meet it? 02:45:20p

Q. Yes. 02:45:22p

A. Yes. 02:45:22p

Q. Okay. Now, let me refer your 02:45:27p

1	**attention to Paragraph 56 of your report.**	**02:45:55p**
2	MR. BONELLA: The first report.	02:46:00p
3	MR. SABER: Yes, we're in the	02:46:01p
4	first report.	02:46:02p
5	BY MR. SABER:	02:46:02p
6	**Q. On Page 21.**	**02:46:02p**
7	A. Okay.	02:46:03p
8	**Q. And you refer to the testimony of**	**02:46:04p**
9	**Mr. Hallet in that paragraph?**	**02:46:11p**
10	A. Yes. Excuse me. Yes.	02:46:13p
11	**Q. I'm sorry.**	**02:46:15p**
12	A. Sorry.	02:46:16p
13	**Q. And you refer to the testimony of**	**02:46:17p**
14	**Mr. Hallet that in the development of FiberWire**	**02:46:21p**
15	**he had constructed a 100 percent homogeneous**	**02:46:25p**
16	**ultra high molecular weight PE braid but Arthrex**	**02:46:29p**
17	**had requested a less stiff braid?**	**02:46:32p**
18	A. That's what I write, yes.	02:46:36p
19	**Q. Okay. Why did you rely upon that**	**02:46:39p**
20	**testimony? Or let me just and then the next**	**02:46:40p**
21	**sentence is, Mr. Hallet then made a heterogeneous**	**02:46:45p**
22	**braid of ultra high molecular weight polyethylene**	**02:46:48p**
23	**and PET to get the strength of ultra high**	**02:46:50p**
24	**molecular weight PET and the flexibility of PET?**	**02:46:53p**
25	A. Yes.	02:46:57p

A. PET has a lower tensile modulus and can affect the tensile stiffness -- I mean, the bending stiffness in a positive fashion. 02:56:30p 02:56:33p 02:56:36p

Q. Do you mean make it easier to bend? **02:56:39p**

A. Easier to bend. 02:56:41p

Q. Right. And -- **02:56:42p**

A. And easier to hold a knot. 02:56:43p

Q. Am I correct that adding the PET to the ultra high molecular weight braid made the braid easier to bend? **02:56:46p 02:56:51p 02:56:55p**

A. That's what people have said, yes. 02:56:58p

Q. Do you believe that to be true? **02:57:00p**

A. I believe that because it has a lower tensile modulus, it could make it easier to bend, that's correct. Modulus, M-O-D-U-L-U-S. 02:57:03p 02:57:07p 02:57:12p

Q. Would you expect that adding the PET would make the braid easier to bend? **02:57:15p 02:57:21p**

A. Adding or substituting? 02:57:23p

Q. Adding -- well, going from an all ultra high molecular weight PE braid -- **02:57:24p 02:57:30p**

A. Right. 02:57:33p

Q. -- to a heterogeneous braid of the combination of ultra high molecular weight PE and PET would make the braid easier to bend; is that what your expectation is? **02:57:34p 02:57:37p 02:57:40p 02:57:45p**

1	A. In the context of this invention or in	02:57:46p
2	general?	02:57:49p
3	**Q. In the context of this invention.**	**02:57:49p**
4	A. In the context of this invention, yes.	02:57:51p
5	**Q. Okay. In the context of this**	**02:57:54p**
6	**invention, is it your opinion that the ultra high**	**02:57:55p**
7	**molecular weight PE braid alone was not easy to**	**02:58:00p**
8	**bend?**	**02:58:05p**
9	A. That it was -- it was -- I'm going by	02:58:06p
10	what Mr. Hallet testified, he said Arthrex	02:58:12p
11	requested a less stiff braid, so he went to a	02:58:14p
12	combination, a tailored combination, yes.	02:58:16p
13	**Q. So that and would that be your**	**02:58:18p**
14	**expectation?**	**02:58:20p**
15	A. That's what I would do.	02:58:20p
16	**Q. In the context of this invention?**	**02:58:21p**
17	A. In the context of this invention.	02:58:23p
18	**Q. You would expect that the ultra high**	**02:58:24p**
19	**molecular weight braid would be -- would not be**	**02:58:26p**
20	**easy to bend?**	**02:58:29p**
21	A. Right.	02:58:30p
22	**Q. Okay.**	**02:58:31p**
23	A. And he solved the problem by going to	02:58:31p
24	what's the novel and basic characteristics of our	02:58:36p
25	invention. The '446, it's not mine.	02:58:43p

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

DePUY-MITEK, INC.,
A Massachusetts Corporation,
Plaintiff,
vs.
ARTHREX, INC.,
A Delaware Corporation,
Defendants.

ORIGINAL

DAY 2 OF 2

DEPOSITION OF DR. DAVID S. BROOKSTEIN

Philadelphia, Pennsylvania

July 27, 2006

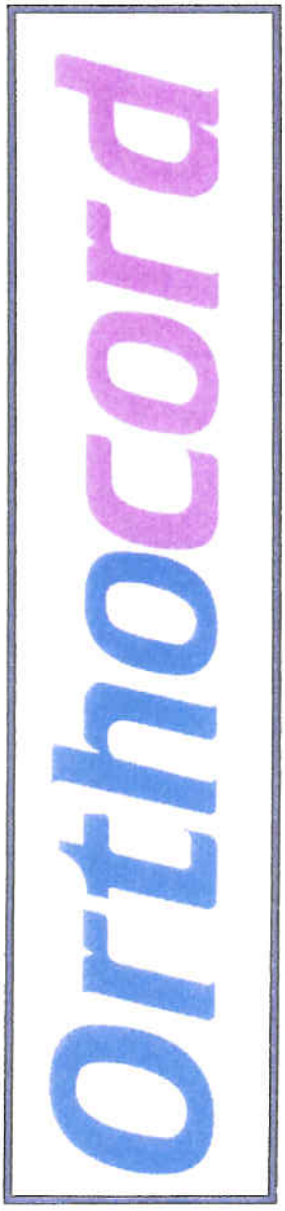
Reported by:

PAMELA HARRISON, RMR, CRR, CSR

1	A. It is my opinion that if the coating	10:24:09a
2	in some miraculous way made those materials not	10:24:11a
3	yarns anymore and they were no -- they were not	10:24:15a
4	dissimilar anymore, that that would be a change.	10:24:17a
5	If all of a sudden what was once a set of two	10:24:22a
6	dissimilar yarns miraculously became, for	10:24:26a
7	instance, a monofilament, that would be a change,	10:24:29a
8	yeah.	10:24:31a
9	**Q. And that would affect the basic and**	**10:24:32a**
10	**novel characteristics?**	**10:24:33a**
11	A. If the basic and novel characteristics	10:24:34a
12	are two dissimilar yarns, yes, and all of a	10:24:35a
13	sudden there weren't yarns in there anymore, it	10:24:38a
14	was some new material that was -- that we don't	10:24:41a
15	know about.	10:24:43a
16	**Q. Or the yarns were the same yarns, made**	**10:24:44a**
17	**the yarns into the same yarns?**	**10:24:46a**
18	A. If they were not dissimilar, right.	10:24:48a
19	**Q. Right. So is it your opinion that if**	**10:24:49a**
20	**the coating does not -- does not achieve the goal**	**10:24:54a**
21	**that you just described, then it does not affect**	**10:25:00a**
22	**the basic and novel characteristics of the**	**10:25:02a**
23	**invention as Dr. Mukherjee defines it?**	**10:25:05a**
24	A. Can you repeat the question.	10:25:07a
25	**Q. Yeah, let me try and rephrase it.**	**10:25:08a**

1	**Is it your opinion that the**	**10:25:12a**
2	**coating -- if the coating does not transform**	**10:25:15a**
3	**the braided material into another structure,**	**10:25:20a**
4	**would you -- let me ask it this way. What do**	**10:25:24a**
5	**you mean when you say transform the braided**	**10:25:27a**
6	**FiberWire materials into another structure?**	**10:25:30a**
7	A. What do I mean?	10:25:32a
8	**Q. Yes.**	**10:25:33a**
9	A. I mean it's not dissimilar yarns	10:25:34a
10	anymore, that would be an example of what I	10:25:36a
11	mean. That all of a sudden you had a set from A,	10:25:38a
12	a set from B and now it was some magical	10:25:41a
13	structure that wasn't yarns, it wasn't two sets,	10:25:45a
14	they were all the same, that would be a	10:25:48a
15	transformation.	10:25:50a
16	**Q. Okay.**	**10:25:52a**
17	A. It would be alchemy, but it would be a	10:25:52a
18	transformation.	10:25:56a
19	**Q. Okay. If that transformation doesn't**	**10:25:56a**
20	**occur by the coating, then is it your opinion**	**10:25:58a**
21	**that the coating doesn't affect the basic and**	**10:26:01a**
22	**novel characteristics of the invention?**	**10:26:02a**
23	MR. BONELLA: Objection.	10:26:04a
24	THE WITNESS: That's not what I	10:26:04a
25	said.	10:26:05a

EXHIBIT 18



It Handles Better!

Q. How can it be as strong but less stiff?

A. PDS is less stiff than HMWPE

A. 50% less HMWPE (than FiberWire™) with PDS core (vs. FiberWire PE core)

A. ORTHOCORD is braided with 16 carriers

⇧ Smaller bundles: More flexible

⇧ 16 bundles in a balanced fiber bundle matrix

Q. How might this impact handling?

A. Less memory/kick back ⇒ Tighter Knot ⇒ Lower Profile?

A. Coated with Ethicon's proprietary NVC coating for improved slide ability and enhanced knot tying characteristics (e.g. knot slide)

Q. Can improved handling result in fewer knots?

EXHIBIT 19

Completion Report for Protocol # ST- 98053

Protocol for the Development of NVC coating on Panacryl™ suture material

Introduction

The purpose of coating the Panacryl braided suture is to provide the suture with good handling properties. These properties are typically evaluated using performance tests such as knot slide, suture roughness, and knot security tests. It has also been shown that some coatings can have an affect on the knot tensile properties of a suture, actually increasing the knot strength.

The protocol for which this completion report is written, evaluated the "braid-in-braid" Panacryl suture according to the aforementioned tests. The coating material used was NVC(90/10 Caprolactone/Glycolide) in Ethyl Acetate. Three unique braid lots were evaluated. One lot was coated at coating levels from 2% to 7% (wt/wt) with the remaining two lots coated at 4%-6% (wt/wt). Analytical testing was performed on the non-sterile unannealed coated braid to determine the amount of coating on the braid (add-on).

Materials and Methods

Three lots of Panacryl size one material were obtained from the Somerville textile group (lot #'s L263BSH, L265BSH, and L266BSH). Lot # L263BSH was coated using 2% through 7% solutions and lots L265BSH and L266BSH were coated using 4% through 6% coating solutions. The coating run summary sheet is shown in Exhibit 1. All materials were coated using the Somerville research coating line dip coating head (identical to the Cornelia Vicryl production dip coating head) and run at 264 ft/min with a

drying tunnel temperature of 120°F. Exhibit 2 describes the rationale for the drying tunnel temperature for Panacryl. The materials were then rack annealed and post pliabilized. Material of sufficient quantity to perform all non sterile testing was separated out and balance of materials was sent through "D" specials for winding, packaging and sterilization. The material was wound in single strand put up and foiled with blank top stock, open vent. The material was exposed to the primary EtO sterilization cycle "F" and secondary sterilization cycle "J". A sample work order for "D" specials is attached as Exhibit 3. The sterile materials were then forwarded to CPC for knot slide, knot security and suture roughness evaluation. The knot slide and suture roughness tests were performed on the lowest coating concentration and if the material did not pass the next higher concentration would be tested. If the material passed at the lowest concentration, no more knot slide or suture roughness testing is required. If the material has acceptable knot slide and suture roughness at a lower coating concentration, the material coated at higher concentrations will have acceptable knot slides and suture roughness, because an increase in coating on the braid can only help the material to slide against itself. This would improve the knot slide and suture roughness results. The knot security testing was performed on the highest coating concentration and if the material did not pass, the next lower concentration would be tested. If the material passed at the highest concentration, no more knot security testing is required. If the material has acceptable knot security at a higher coating concentration, the material coated at lower concentrations will have acceptable knot security, because a decrease in coating on the braid can only help to secure the knot.

Sterile materials were also evaluated for diameters and tensile strength by Suture technologies.

Results

A summary of results for the Suture technology testing (diameters and tensile) are shown as Appendix 1. All non-sterile samples, with the exception of the material coated at 2%, exceeded the raw material minimum requirements for straight and knot tensile strength. The average straight tensile strength ranged from 23.49 to 25.02 lbs., and size 1 has a

minimum average requirement of 20.04 lbs. The average knot tensile strength ranged from 11.87 to 12.70 lbs., and size 1 has a minimum average requirement of 11.79 lbs. The non-sterile material diameters were in the range of 21.0 to 21.6 mils, and are also within the material average requirements range of 19.68 to 22.25 mils. The sterile materials all exceeded the finished goods minimum requirements for straight and knot tensile strength. The sterile material diameters were also within the material requirements with diameters in the range of 20.9 to 21.7 mils. The test results from the knot slide tests are attached as Appendix 2. The three lots were tested at the lowest coating concentrations (L263@2%, L265@4%, and L266@4%) and all had acceptable knot slide of 10 slides out of 10 attempts. The knot security test results are attached as Appendix 3. The three lots were tested at the highest coating concentrations (L263@7%, L265@6%, and L266@6%) and all three lots were secure at four throws. The suture roughness test results are attached as Appendix 4. The suture roughness on all three lots was acceptable.

The coating add on test results are shown as Appendix 5. The coating add on values ranged from 0.48% to 1.83% (weight of coating/weight of braid). The braid with the 0.48% add on (coated with 2% coating solution) had acceptable knot slide and the braid with the 1.83% add on (coated with 7% coating solution) had four throw knot security.

Discussion

The test results from the straight and knot tensile testing document that the braid meets the USP requirements for size 1, with regards to tensile strength. The diameter range for size 1 Panacryl is 19.68 to 22.25 mils. The diameter range recorded in this study was from 20.9 mils to 21.7 mils, which is within the required range.

The knot slide test results document the functionality of the coating at the lower coating concentrations of 2% and 4%. All tested specimens satisfied the 10/10 knot slide requirement. The knot slide forces were documented for all specimens tested.

The knot security test results document the functionality of the coating at the higher coating concentrations of 6% and 7%. All tested specimens satisfied the 0/20 slip through, 18-20/20 knot secured and 0-2/20 slip break requirements at four throws.

The suture roughness test results are provided for informational purposes. There is no suture roughness requirement, however, the Panacryl test results were comparable to values typical for size 1 coated Vicryl™.

The coating concentrations used in this study ranged from 2% to 7%. All three lots were coated at 4,5, and 6% coating solution. It was documented that the Panacryl material functioned when coated with solutions from 2% through 7%. To provide a conservative range of target coating concentrations the outer ends of the coating concentrations will be moved in to 4% to 6%, with a target (nominal) of 5%. The add on range will be determined by using the add ons from one concentration away from the 4% - 6% target range (3% and 7%) to allow for manufacturing ability.

Conclusions

From the results of this study it can be concluded that the Panacryl™ suture meets or exceeds the requirements of this study. The Panacryl™ material was functional when coated with NVC coating in Ethyl Acetate at coating solutions concentrations of 2% to 7% (wt/wt) and coating add ons of from 0.48% to 1.83%(wt/wt). It is therefore recommended that the coating solution range be from 4% to 6% with a nominal coating concentration of 5%. The add on ranges recommendation is from 0.7% to 1.8%.

Approvals

1/24/99

Jerry Fischer
Engineering Fellow

1/25/99

Howard Scalzo
Senior Engineer

EXHIBIT 20

JOURNAL OF SURGICAL RESEARCH 35, 525–530 (1983)

Knotting and Handling Characteristics of Coated Synthetic Absorbable Sutures

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The purpose of this study was to evaluate the knotting and handling characteristics of the new coated synthetic absorbable sutures. When compared to the coated polyglactin 910 sutures, the coated polyglycolic acid sutures displayed a lower coefficient of friction, encountered less tissue drag forces, and exhibited less flexural rigidity. In the case of sizes O, 2-O, and 3-O coated polyglycolic sutures, knot security was achieved with one less throw than with similar sizes of coated polyglactin 910 sutures. On the basis of these comprehensive mechanical performance tests, the knotting and handling characteristics of the coated polyglycolic acid sutures were judged to be superior to that of the coated polyglactin 910 sutures.

INTRODUCTION

As an alternative to gut sutures, two new synthetic absorbable sutures have been introduced for wound closure. These two sutures are very similar in their physical and chemical configuration. One suture is braided from filaments of polyglycolic acid while the other is braided from a copolymer of glycolic acid (90%) and lactic acid (10%). In most clinical situations these synthetic sutures have proven to be superior to gut sutures with respect to strength retention, tissue reactivity, incidence of postoperative complications, and influence on wound healing [3]. However, the surfaces of these synthetic absorbable sutures display a high coefficient of friction that makes tying difficult. When tying these sutures, surgeons may find themselves frustrated by their inability to set or advance a two-throw square knot. When the two-throw knot locks prematurely, the surgeon will usually break the suture as he tries to advance the knot. The rough suture surface also causes the suture to drag through tissue [1] making it difficult to adjust tension on a continuous running surface.

[1] To whom reprint requests should be addressed.

Recently, the surfaces of these synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics. A comprehensive analysis of the mechanical performance of these coated synthetic sutures was conducted. This critical analysis of sutural performance determined the number of throws needed to achieve knot security, the expected slippage of the knot in its secure configuration, the coefficient of friction, and tissue drag as well as the suture's flexural rigidity and memory.

MATERIALS AND METHODS

Three types of sutures were evaluated in this study. Dexon "S" (Davis & Geck, Wayne, N. J.) is a braided polyglycolic acid suture without coating. Dexon Plus (Davis & Geck) has the same construction as Dexon "S" but is treated with an absorbable surface lubricant, Poloxamer 188. Coated Vicryl (polyglactin 910) (Ethicon, Inc., Somerville, N. J.) sutures are braided filaments of the copolymer of polyglycolic acid and lactic acid which have been coated with an absorbable mixture of calcium stearate and a copolymer of lactic acid (65%) and glycolic acid (35%). The su-

0022-4804/83 $1.50

tures were obtained from individual suppliers and tested as received from their individual sterile packages. The sutures evaluated were in sizes O, 2-O, 3-O, 4-O, and 5-O. The diameter of each suture was measured without compression. The suture was mounted under a microscope and its magnified image was displayed on a calibrated television screen and its thickness measured.

KNOT PERFORMANCE

The mechanical performance of a knotted suture can be measured, in part, by its knot-holding strength, its knot slippage, and the number of throws required to complete a knot that will reach break [5]. In this study, reproducible knots were mechanically tied at a constant rate of loading with predetermined tension using an Instron Tensile Tester. Tying the knot under known tensions eliminates the variability encountered with hand-tied knots. The tying of a reproducible square knot (1 = 1) was accomplished by forming the knot without subjecting its ears to any appreciable tension. The formed knot was then secured utilizing a tension equivalent to 85 ± 5% of the specific knot-holding tension. This tension is similar to that utilized by a surgeon who carefully snugs each throw tightly together.

The tension was applied to the knot using the Instron Tensile Tester. One ear of the knot was secured to the upper jaw of the tensile tester while the other ear of the knot was attached to a weight equivalent to the predetermined tension to be used to tie the knot. The weight was lifted off the lower jaw by the attached suture at a rate of 2 mm/min. The total load remained on the knot for 10 sec to complete the tying of the first two throws of the knot. When additional throws were being tested, the procedure was repeated for each throw. Each additional throw was formed so that its configuration was square (1 = 1 = 1 · · ·) in reference to the previous throw. No tension was placed on the patient's side of the knot.

After completing the knot, the loop was divided at its midpoint. The loop ends were then positioned in the jaws of the tensile tester so that the test section was taut and that the knot was centered in the 51-mm jaw separation. The knot was then loaded until knot break at an extension rate of 20 mm/min. The knot-holding capacity was recorded as the maximum load value on the load extension curve before knot breakage and/or infinite slippage.

Slippage for all tests was determined at the level of the 95% confidence limit for knot-holding capacity. At this level the slippage was obtained by subtracting the mean elongation value of sutures without a knot subjected to the desired load from the mean elongation value of knotted sutures under the same load.

ANALYSIS OF KNOT SECURITY

A secure knot was defined as a knot that went to knot break without slipping more than 3.0 mm. The minimum load at which 95% of the knotted sutures can be expected to survive without breaking was defined as the 95% knot break load (KBL_{95}). KBL_{95} was determined from the number of samples tested, the mean knot break load ($\overline{KBL}$), and the standard deviation (SD_{KBL}). Due to the small number of samples tested (10 to 12) for each suture size, the data were assumed to follow the form of a "t" distribution. Using tabulated "t" values, KBL_{95} was determined by the equation:

$$KBL_{95} = \overline{KBL} - t(SD_{KBL}).$$

At KBL_{95}, mean knot slippage ($\overline{KS}$) was determined from the difference between mean elongation of the sutures without a knot (E_{wo}) and mean elongation of the sutures with a knot (E_w):

$$\overline{KS} = E_w - E_{wo},$$

where $E_w \geq E_{wo}$.

The maximum slippage that would be expected to occur in 95% of the knotted sutures at KBL_{95} was defined as MKS_{95} and was determined in a similar manner to KBL_{95} by using the formula

$$MKS_{95} = \overline{KS} + t(SD_{KS}).$$

After determining the mean break load ($\overline{BL}$) and standard deviation of unknotted suture, the lower 95% confidence limit was determined using the formula

$$BL_{95} = \overline{BL} - t(SD_{BL}),$$

where BL_{95} = the minimum load that 95% of unknotted sutures can be exposed to without breaking.

Knot efficiency is an indication of how efficiently the knot utilizes the strength of the suture material. A knot that did not reduce the breaking value of a suture would have a knot efficiency of 100%. Thus knot efficiency can be determined by

$$\text{knot efficiency} = \frac{KBL_{95}}{BL_{95}}.$$

COEFFICIENT OF FRICTION

The knotting profile of all suture materials is dependent in part on the frictional forces operating at the surface of the overlapping strands. In this study, an estimate of the frictional forces encountered during knot tying was measured using the Instron Tensile Tester. The coefficients of friction was calculated from the ratio of forces needed to pull one suture strand across itself at a right angle when one strand was under a constant load. For this experiment size 3-O sutures were evaluated.

TISSUE DRAG

Another aspect of frictional forces acting at the suture surface is the force required to pull the suture through tissue. In this experiment a standard model involving the surgically prepared paravertebral skin of the rabbit was used. On each side of the spine a pair of parallel lines was drawn that were 30 mm apart. Each pair of longitudinal lines was connected by a series of perpendicular lines separated by 10 mm. For this experiment, size 3-O sutures swaged to straight cutting needles (CS-1 for Dexon; KS for Vicryl) were used. The needle and suture were passed transversely through the dermis beneath one of the lines for a distance of 30 mm. After exiting from the skin, the needle reentered the skin 10 mm caudad to its exit point and was passed back through the dermis for another 30 mm until it exited 10 mm caudad to its original point of entrance. The needle was then attached to a continuous drive strain gauge that recorded the force necessary to pull the suture through the tissue at a constant rate of 88 mm/min. The mean pull through force was determined from the load curve.

FORCE REQUIRED TO STRAIGHTEN COILED SUTURES

Packaging of the suture strands requires that the suture be folded several times. When the suture material has memory, the suture remains kinked after removal from its package. Stretching the suture under a load such as a quick jerk sometimes erases this memory. In this experiment the minimum load required to erase the memory was determined. After removal of the suture strand from its package a loop was tied in the end of the size 3-O suture. The loop was placed over a known weight and the weight lifted at a rate of 20 mm/min until the weight was hanging free. The suture was exposed to the load for 15 sec before being released. If the suture still remained kinked, more weight was added and the process was repeated until the suture hung straight immediately after removing the weight. This process was repeated with 10 samples of each suture.

STIFFNESS

Suture stiffness is an important parameter that significantly influences the handling characteristics of the suture. An indication of suture rigidity was obtained by calculating the product of the suture area moment of inertia I and the modulus of elasticity of the material (E).

The modulus of elasticity E was determined from the slope of the tangent drawn to the load extension curve at a load of 17.68 N. 17.68 N was the KBL_{95} for 3-O coated polyglactin 910 and was lower than that for

either of the polyglycolic acid sutures. The assumption was made that the suture materials were homogeneous throughout their cross-sectional area. The load extension curves were obtained from 50-mm gauge-length samples that were loaded at a constant extension rate of 20 mm/min. The area moment of inertia (I) calculation assumed the sutures had a round cross-sectional area and

$$I = \frac{\pi D^4}{64},$$

where D = suture diameter.

Thus stiffness or the product of E and I results from the reduced equation:

$$\text{stiffness} = EI = \frac{(K)GD^2}{16},$$

where

E = modulus of elasticity (MPa),
I = area moment of inertia (mm^4),
K = slope of the tangent drawn to the load extension curve at KBL_{95} (N/mm),
G = gauge length (mm), and
D = suture diameter (mm).

RESULTS

The mechanical performance data for the three synthetic absorbable sutures are presented in Table 1. For the uncoated polyglycolic acid suture, the number of throws required to form a square knot that fails at knot break with slippage equal to or less than 3 mm was two throws (1 = 1) regardless of suture size. When this suture was coated, knot security was only accomplished with a square knot construction comprised of four throws (1 = 1 = 1 = 1) for all suture sizes tested. In the case of O, 2-O, and 3-O coated polyglactin 910 sutures, five throws square (1 = 1 = 1 = 1 = 1) were necessary to achieve knot security. A four-throw square knot construction (1 = 1 = 1 = 1) was required for knot security for the smaller-size coated polyglactin 910 sutures (4-O and 5-O).

Coating the polyglycolic acid suture did not significantly alter its knot-break strength. However, the breaking strength of unknotted, uncoated polyglycolic acid sutures was unusually higher than that of the unknotted, coated polyglycolic acid sutures. This disproportionate increase in the breaking strength

TABLE 1

KNOT PERFORMANCE VALUES

Type of suture	Suture size	Suture diameter (μm)	Knot security (No. throws)	KBL_{95}[a] (N)	MKS_{95}[a] (N)	BL_{95}[a] (N)	Knot[a] efficiency (%)
Uncoated polyglycolic acid	O	482 ± 2	2	4576	3.0	8926	51
	2-O	453 ± 5	2	3802	3.0	6468	59
	3-O	343 ± 3	2	2055	2.9	3873	53
	4-O	284 ± 2	2	1329	1.6	2514	53
	5-O	192 ± 2	2	755	3.0	1403	54
Coated polyglycolic acid	O	527 ± 15	4	4451	2.4	7259	61
	2-O	450 ± 6	4	3536	2.0	6163	57
	3-O	302 ± 4	4	1962	2.2	2931	67
	4-O	302 ± 7	4	1408	2.2	2084	69
	5-O	227 ± 5	4	801	1.9	1469	55
Coated polyglactin 910	O	469 ± 8	5	3742	3.0	7793	48
	2-O	394 ± 2	5	2816	3.0	6127	46
	3-O	293 ± 1	5	1768	1.2	3714	48
	4-O	235 ± 1	4	1169	1.9	2512	46
	5-O	179 ± 1	4	625	2.3	1398	45

[a] See text for definitions: KBL, knot break load; MKS, maximum knot slippage; BL, unknotted break load.

of the unknotted, uncoated suture as compared to that of the coated suture accounts for the increased knot efficiency of the coated sutures. The knot-break strength as well as knot efficiency for the coated and uncoated polyglycolic acid sutures was greater than that for the polyglactin 910 sutures. This low level of knot break strength for coated polyglactin 910 sutures is due in part to their smaller diameter. When identically labeled suture sizes were measured without compression, the diameters of the polyglactin 910 sutures were uniformly smaller than those of the coated and uncoated polyglycolic acid sutures.

Coating the sutures had other measurable effects on their handling characteristics (Table 2). The coatings reduced the frictional forces encountered when the surface of a specific suture was drawn across itself. In size 3-O, the coefficient of friction for coated polyglycolic acid sutures was significantly less than that for the uncoated suture. The coefficient of friction for the coated polyglycolic acid suture was lower, but did not differ significantly from that of the coated polyglactin 910 sutures. These *in vitro* studies correlated with the *in vivo* measurement of the force required to pass the sutures through tissue. The mean force required to pull uncoated polyglycolic acid suture through tissue was 4.97 ± 0.54 N as compared to a tissue drag force of only 0.61 ± 0.14 N for the coated polyglycolic acid suture. This low level of tissue drag encountered with coated polyglycolic acid sutures was significantly ($P < 0.001$) less than that encountered by the coated polyglactin 910 sutures (3.04 ± 0.31 N).

Other interesting differences between the handling characteristics of these sutures were noted. The rigidity of the coated polyglactin 910 sutures was the greatest, followed by the uncoated polyglycolic acid sutures and then the coated polyglycolic acid sutures. The stiffness of the polyglactin 910 sutures was also associated with considerable resistance to straightening. The load required to straighten coiled polyglactin 910 sutures was significantly greater than that needed for coiled polyglycolic acid sutures. The forces required to straighten coiled polyglycolic acid coated and uncoated sutures did not differ significantly.

DISCUSSION

The surfaces of synthetic absorbable sutures, until now, exhibited a high coefficient of friction which made them difficult to tie [4]. In addition, their rough surfaces resisted easy passage through tissue [1] which complicated wound closure with a continuous suture. To improve their handling characteristics, coatings were applied to their surfaces to alter their mechanical performance. These coatings serve as lubricants that reduce the frictional forces on the suture surface. Using these new coated synthetic sutures the surgeon now can easily advance a two-throw knot to approximate the wound edges. Once the tissue is meticulously coapted, the surgeon can then tie the additional throws required for knot security. In addition, the coatings have reduced the force required to pull the suture through the tissue making passage of a running coated suture considerably easier. When

TABLE 2

HANDLING CHARACTERISTICS OF SUTURES

Parameter	Suture (3-O)		
	Uncoated polyglycolic acid	Coated polyglycolic acid	Coated polyglactin 910
Coefficient of friction	0.1907 ± 0.0077	0.1296 ± 0.0062	0.1362 ± 0.0063
Tissue drag (N)	4.97 ± 0.54	0.61 ± 0.14	3.04 ± 0.31
Stiffness (N m^2 × 10^6)	1.84	1.14	2.41
Straightening force (N)	6.37	7.84	14.71

comparing the tissue drag encountered by the two coated synthetic sutures in our study, coated polyglycolic acid sutures produced significantly less frictional forces during tissue passage than did coated polyglactin 910.

In light of these advantages, a potential shortcoming of these coatings must be considered. Since a greater number of throws are required to reach knot security with coated sutures than with the uncoated suture, wound closure with coated sutures will involve a larger amount of suture material. This increase in suture material damages host defenses and invites the development of infection [2]. The magnitude of this increase in suture material for sizes O, 2-O, and 3-O is less for coated polyglycolic acid sutures than for coated polyglactin 910 since knot security with the coated polyglycolic acid sutures is achieved with one less throw.

Those surgeons who try to limit the amount of suture material used for wound closure can still resort to the use of uncoated polyglycolic acid sutures in which knot security can be achieved with only two throws. In addition to reducing the risk of infection, this parsimonious use of uncoated suture should decrease the length of the operation. This alternative is not available for the polyglactin 910 sutures since the uncoated suture is no longer commercially available.

The coated and uncoated polyglycolic acid sutures have other special handling characteristics that the surgeon will find attractive. They are supple sutures that can be easily straightened after removal from the package. In contrast, the coated polyglactin 910 sutures are stiff and possess a memory that responds only to forces that approach the breaking strength of the suture. The implications of this sutural rigidity of polyglactin 910 sutures are several. As the surgeon attempts to straighten this coiled suture, he may break the suture. Furthermore, knots constructed with a stiff suture have a tendency to become untied unless each throw is carefully snugged upon the preceding throw. The cause of the extreme flexural rigidity of the polyglactin suture is uncertain. It may be due either to its composition, construction, or the coating material. Since the uncoated polyglactin 910 suture is not commercially available, the latter hypothesis could not be tested in this study.

While this study focused on the performance of the synthetic absorbable sutures at surgery, the influence of tissue implantation on knot performance remains to be studied. It is hoped that the *in vitro* knot security of the coated and uncoated synthetic sutures will persist in the wounded tissue. This supposition is presently being examined in animal models and will be the subject of a future report.

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4. Rodeheaver, G. T., Thacker, J. G., and Edlich, R. F. Mechanical performance of polyglycolic acid and polyglactin 910 synthetic absorbable sutures. *Surg. Gynecol. Obstet.* 153: 835, 1981.
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EXHIBIT 21

DePuy Mitek's Privileged Document List
Civil Action No. 04-12457 PBS

January 25, 2006

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
1	09/20/02	Presentation			Attorney-Client	DMI001096A and DMI001098A: Redacted portions relate to legal advice concerning patent searches and results
2	11/21/03	Presentation			Attorney-Client	DMI001015A: Redacted portion relates to legal advice concerning patent searches and results
3	05/22/03	Presentation	George Cook		Attorney-Client	DMI001068A, DMI001070A, DMI001071: Redacted portions relate to legal advice concerning assessment of issued patents.
4	11/21/03	Presentation	Unknown		Attorney-Client	DMI001041A: Duplicate of privileged document #2
5	05/22/03	Presentation	George		Attorney-Client	DMI001083A, DMI001089, DMI001090A: Redacted portions relates to legal advice concerning issued patents
6	05/22/03	Presentation	George		Attorney-Client	DMI000981, DMI000984, DMI000992A: Redacted portions relate to legal advice concerning impact of issued patents
7	11/25/03	Presentation	McAlister Cook		Attorney-Client	DMI000973 and DMI000976: Redacted portions relate to legal advice concerning impact of issued patents
8	05/14/04	Report	Seppa		Attorney-Client	DMI000455: Redacted portion relates to legal advice concerning issued patents
9	09/23/97	Letter	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
10	10/20/97	Letter	Woodrow*	Groening*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
11	09/23/97	Letter with handwritten notes	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
12	09/23/97	Letter with handwritten notes	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
13	09/23/97	Letter with handwritten notes	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
14	06/07/96	Letter	Groening*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
15	01/22/96	Letter	Woodrow*	Fritzsche*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
16	12/05/95	Letter	Fritzsche*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
17	07/08/93	Memo with notes	Clickner	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning German Hunter patent application
18	07/22/02	Letter	Yasuda*	Wissing*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
19	07/17/01	Letter	Wissing*	Yasuda*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
20	07/17/01	Letter with notes	Wissing*	Yasuda*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
21	04/27/01	Letter	Yasuda*	Weiss*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
22	04/26/01	Letter	Yasuda*	Woodrow*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
23	04/02/03	Letter	Yasuda*	Wissing*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
24	06/25/03	Letter	Yasuda*	Loo*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
25	06/13/03	Letter with notes	Loo*	Odajima*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
26	06/13/03	Email	Palko*	Odajima*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
27	06/11/03 06/11/03	Email Email	Loo* Loo*	Odajima* Palko*	Attorney-Client Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
28	06/11/03	Email	Loo*	Odajima*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
29	04/02/03	Letter	Yasuda*	Wissing*	Attorney-Client	Communication reflecting legal advice concerning Japanese Hunter patent application
30	06/21/04	Report	Burkley	Seppa Howe	Attorney-Client/ Work Product	Communication seeking legal advice regarding patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
31	Undated	Draft Invention Disclosure	Koyfman Brucker Hill		Attorney-Client	Communication to counsel seeking legal advice concerning patentability of invention
32	07/15/04	Memo	Seppa	Skula* McAlister Leibowitz	Attorney-Client/ Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.

*=Attorney/Paralegal/Patent Agent

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
33	08/19/04	Memo	Seppa	Skula* McAlister Leibowitz	Attorney-Client/ Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
34	02/18/04	Report	Seppa	Distribution	Attorney-Client/Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
35	11/25/03	Presentation	McAlister Cook		Attorney-Client	DMI006571: Redacted portion relates to legal advice concerning issued patents
36	11/08/02	Report	Longstreet	Ethicon GMB	Attorney-Client	DMI038171: Redacted portion relates to communication seeking legal advice concerning the patentability of an invention.
37	08/07/03	Plan			Attorney-Client	DMI039134: Redacted portion relates to reflecting legal advice concerning third party patent rights
38	Undated	Presentation			Attorney-Client	DMI0039239: Redacted portion relates to legal advice concerning Orthocord patent claims
39	Undated	Presentation			Attorney-Client	DMI39400: Redacted portion relates to request for legal advice concerning issued patents
40	09/02/03	Report	Koyfman Pokropinski		Attorney-Client	DMI039422: Redacted portion reflects legal advice concerning scope of issued patents
41	09/24/03	Report	Koyfman Pokropinski		Attorney-Client	DMI039447: Redacted portion reflects legal advice concerning scope of issued patents
42	11/04/02	Report	Dormier		Attorney-Client	DMI039473, DMI039474, DMI039475, DMI039486 and DMI039490: Redacted portions reflects legal advice concerning scope of issued patents
43	11/05/01	Report	Longstreet		Attorney-Client	DMI039496-97: Redacted portions reflects legal advice concerning scope of pending patent applications
44	02/27/03	Presentation			Attorney-Client	DMI039501, DMI039508 and DMI039513: Redacted portions reflect legal advice concerning issued patents and freedom to operate
45	09/02/04	Outline	Seppa		Attorney-Client/ Work Product	DMI039518: Redacted portion reflects legal advice and work performed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
46	Undated	Notes			Attorney-Client	DMI039558: Redacted portion relates to reflects legal advice concerning issued patents

*=Attorney/Paralegal/Patent Agent

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
47	07/26/04	Outline			Attorney-Client/ Work Product	DMI039560: Redacted portion reflects legal advice and work performed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
48	06/29/04	Outline			Attorney-Client/ Work Product	DMI039571: Redacted portion reflects legal advice and work performed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
49	07/28/03	Report	Koyfman		Attorney-Client	DMI039621: Redacted portion reflects legal advice concerning issued patents
50	04/13/04	Presentation			Attorney-Client/ Work Product	DMI039675 and DMI039678: Redacted portion reflects legal advice concerning issued patents and pending patent application and reflects work performed at the direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
51	09/26/03	Report	Nozad		Attorney-Client	DMI039707: Redacted portion reflects request for legal advice concerning pending patent third party applications
52	Undated	Presentation			Attorney-Client	DMI039726 and DMI039747: Redacted portions relate legal advice concerning pending patent application and analysis of third party patent rights
53	Undated	Presentation			Attorney-Client	DMI039759: Redacted portions relate to legal advice concerning analysis of third party patent rights
54	5/27/04	Report	Seppa	Distribution	Attorney-Client/Work Product	Communication to counsel seeking legal advice concerning patent infringement and reflecting work preformed at direction of counsel in anticipation of patent litigation with Arthrex concerning the Hunter patent.
55	Undated	Filed Application with handwritten notes	Matthew Goodwin*		Attorney Client	Notes reflect Examiner's comments and proposed amendments and attorney analysis of the same in furtherance of providing legal advice concerning patentability of invention
56	12/2/91	Letter	Matthew Goodwin*	M. Steckel	Attorney-Client	Communication reflecting legal advice concerning patent application
57	7/26/93	Letter	Dennis Jamiolkowski	Hal Woodrow* Donald Regina	Attorney-Client	Communication to counsel in furtherance of providing legal advice concerning response to Office Action from the USPTO
58	8/3/92	Letter	A. Hunter	Matthew Goodwin*	Attorney-Client	Communication to counsel in furtherance of providing legal advice concerning a response to an Office Action from the USPTO

*=Attorney/Paralegal/Patent Agent

Tab	Date	Document	Author	Recipient	Privilege Claimed	Description
59	12/20/91	Letter	Charles Fritz	Matthew Goodwin* M. Steckel	Attorney-Client	Communication to counsel seeking legal advice concerning the patentability of invention
60	6/4/91	Letter	Matthew Goodwin*	M. Steckel	Attorney-Client	Communication from counsel reflecting legal advice concerning the patentability of invention
61	11/18/91	Letter	Mark Steckel	Matthew Goodwin* A. Finkenaur R. Lilenfeld B. Schwartz A. Skinner	Attorney-Client	Communication to counsel seeking legal advice concerning the patentability of invention
62	7/14/92	Letter	Matthew Goodwin*	A. Hunter D. Jamiolkowski	Attorney-Client	Communication from counsel seeking information in connection with rendering legal advice concerning a response to an Office Action from the USPTO
63	11/20/92	Letter	A. Hunter	Matthew Goodwin*	Attorney-Client	Communication to counsel seeking legal advice concerning the patentability of invention
64	11/13/92	Letter with handwritten comments	Matthew Goodwin*	Al Hunter Dennis Jamiolkoski	Attonrey-Client	Communication from counsel in connection with providing legal advice concerning the patentability of invention and handwritten notes reflecting conversations concerning patentability of invention
65	11/15/93	Letter to File	Hal Woodrow*	File	Attorney-Client	Communication from counsel reflecting legal advice concerning analysis of Examiner's amendment and inventorship issues
66	Undated	Filed Application with handwritten notes	Hal Woodrow*		Attorney-Client	Notes reflect Examiner's comments and proposed amendments and attorney analysis of the same in furtherance of providing legal advice concerning patentability of invention
67	Undated	Filed Application with handwritten notes	Matthew Goodwin*		Attorney-Client	Notes reflect Examiner's comments and proposed amendments and attorney analysis of the same in furtherance of providing legal advice concerning patentability of invention
68	Undated	Letter to File	Hal Woodrow*	File	Attorney-Client	Communication from counsel reflecting legal advice concerning analysis of art cited abroad
69	1/8/90	Invention Disclosure Memorandum	Mark Steckel	Dr. C. Fritz Mr. A. Hunter Mr. D. Jamiolkowski Mr. D. Rembert Dr. B. Schwartz Dr. A. Skinner	Attorney-Client	Communication forwarded to counsel seeking legal advice concerning the patentability of invention

*=Attorney/Paralegal/Patent Agent

EXHIBIT 22

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

A. If the Novel And Basic Characteristics Have The Definitions Provided By Dr. Mukherjee, FiberWire's Coating Does Not Materially Affect Them

23. According to Dr. Mukherjee, the novel and basic characteristics are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). Dr. Mukherjee opines that FiberWire's coating materially affects this novel and basic characteristic. I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a "material" affect on the basic and novel characteristics; and (iii) Dr. Mukherjee's tests are flawed or inconclusive. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

24. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface "lubricant" (Mukherjee Res. Report at Ex. 16).

materials to optimize all these properties in the product?
A. Yes.

(Ex. I at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
A. All materials used.

(Ex. T at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

27. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. U at 119:5-9; Ex. V at 94:2-9; Ex. W at 48:1-50:16; Ex. X at ARM2104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters

[3] Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

per minute (Ex. U at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. U at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. U at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. U at 95:14-17). The process is then repeated. I have measured the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DM Exhibits 284, 342, and 285). I determined that the linear density of Ex. 284 (uncoated) is 2393 denier, Ex. 342 (coated once) is 2474 denier, and Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from Ex. 342. Thus, the total pick-up of Ex. 285 over Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Mukherjee Res. Report at Ex. 16).

coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

31. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Dr. Mukherjee, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Dr. Mukherjee.

32. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. D at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (Ex. D at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

33. I disagree with Dr. Mukherjee's opinion that FiberWire's coating has a "material" effect because he basically *excludes* coated sutures from the 446 Patent claims (Mukherjee Res. Report at 22). But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to ***further*** improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. ***Most preferably***, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating ***may be*** eliminated saving expense as well as avoiding the associated braid stiffening.

(Ex. D at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them, as Dr. Mukherjee opines. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

34. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Dr. Mukherjee attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set of continuous and discrete yarns (Ex. D at 2:40-41). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (Ex. D at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (Ex. D at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. V at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. D at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. E-G attached to my first report and CETR's images. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as

EXHIBIT 23

United States Patent [19]

Mattei et al.

[11] **Patent Number: 4,532,929**

[45] **Date of Patent: Aug. 6, 1985**

[54] **DRY COATING OF SURGICAL FILAMENTS**

[75] Inventors: **Frank V. Mattei**, Piscataway; **Donald W. Regula**, Flagtown, both of N.J.

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **633,759**

[22] Filed: **Jul. 23, 1984**

[51] **Int. Cl.**[3] **A61L 17/00**

[52] **U.S. Cl.** **128/335.5**; 427/2; 428/263; 428/378

[58] **Field of Search** 128/335, 335.5; 428/263, 378; 427/2

[56] References Cited

U.S. PATENT DOCUMENTS

3,478,140	11/1969	Kronenthal et al.	128/335.5
4,027,676	6/1977	Mattei	128/335.5
4,047,533	9/1977	Perciaccante et al.	128/335.5
4,105,034	8/1978	Shalaby et al.	128/335.5
4,201,216	5/1980	Mattei	128/335.5

Primary Examiner—Jacqueline V. Howard
Attorney, Agent, or Firm—Charles J. Metz

[57] ABSTRACT

Braided or monofilament surgical filaments are coated with dry, powdered, substantially water-insoluble, absorbable salt of a C_6 or higher fatty acid, such as calcium stearate.

20 Claims, No Drawings

DRY COATING OF SURGICAL FILAMENTS

TECHNICAL FIELD

This invention relates to a dry, absorbable composition useful as a coating and lubricating finish for surgical filaments, and to a method for using said composition. More particularly, this invention relates to a means for improving the tie-down properties of absorbable and non-absorbable monofilament surgical filaments as well as multifilament surgical filaments by coating them with a dry, absorbable lubricating composition.

BACKGROUND ART

Suture materials and other surgical filaments such as ligatures are generally classified as either absorbable or non-absorbable, with each type of suture material being preferred for certain applications. Absorbable suture materials are preferred for internal wound repair in which the sewn tissues will hold together without suture reinforcement after healing and in which a nonabsorbed suture may promote tissue irritation or other adverse bodily reaction over an extended period of time. Suture materials are considered to be absorbable if they disappear from the sewn tissue within about a year after surgery, but many absorbable suture materials disappear within shorter periods.

The earliest available absorbable suture materials were surgical gut and extruded collagenous materials. More recently, absorbable sutures derived from synthetic polymers have been developed which are strong, dimensionally uniform, and storage stable in the dry state. Typical of such polymers are lactide homopolymers and copolymers of lactide and glycolide such as those disclosed in U.S. Pat. No. 3,636,956, and glycolide homopolymers such as those disclosed in U.S. Pat. No. 3,565,869.

Monofilament synthetic absorbable suture materials are generally stiffer than their multifilament surgical gut or collagen counterparts, and synthetic absorbable sutures are therefore usually employed in a multifilament, braided construction in order to provide the suture with the desired degree of softness and flexibility. Such multifilament sutures exhibit a certain degree of undesirable roughness or "grabbiness" in what has been termed their "tie-down" performance, i.e., the ease or difficulty of sliding a knot down the suture into place, or the ease of snugging a square knot in place.

Multifilament nonabsorbable sutures such as braided sutures of polyethylene terephthalate, for example, can be improved with respect to tie-down performance by coating the external surface of the suture with solid particles of polytetrafluorethylene and a binder resin as disclosed in U.S. Pat. No. 3,527,650. This procedure, however, is undesirable as applied to absorbable sutures because polytetrafluoroethylene is nonabsorbable and sutures coated therewith would leave a polymer residue in the sewn tissue, after the suture had been absorbed.

Multifilament, nonabsorbable sutures can also be improved with respect to tie-down performance by coating them with a linear polyester having a molecular weight between about 1,000 and about 15,000 and at least two carbon atoms between the ester linkages in the polymer chain as disclosed in U.S. Pat. No. 3,942,532.

U.S. Pat. No. 3,297,033 discloses that the synthetic absorbable sutures described therein may be coated with conventional suture coating materials such as a silicone or beeswax in order to modify the handling or absorption rate of the sutures. These coating materials are not readily absorbable, however, and will accordingly leave an undesirable residue in the tissue after the suture itself is absorbed.

Many other compounds have been proposed as treating agents to improve the lubricity and handling of both natural and synthetic filaments. U.S. Pat. No. 3,896,841 describes the treatment of collagen sutures with a hygroscopic agent and lubricant to provide a suture which permanently retains at least 10 percent by weight moisture. Sutures so treated are reported to have increased suppleness and reduced drag when passing through tissue. Fatty compounds and derivatives of fatty compounds are suggested as useful lubricating agents for such collagen sutures.

U.S. Pat. No. 3,982,543 discloses that multifilament, absorbable sutures may be lubricated/coated with a copolymer of lactide and glycolide in order to reduce the capillarity of the suture, and that sutures so treated are reported to have improved run down.

Because of the nature of surgical procedures, sutures and ligatures are generally exposed to body fluids or passes one or more times through moist tissue before tying, and an effective suture coating composition ideally provides wet tie-down characteristics substantially equivalent to those of the dry suture.

U.S. Pat. No. 4,143,423 discloses coating surgical applicances with a gloving agent or lubricant comprising a water soluble nontoxic alkali metal compound such as sodium bicarbonate. The compound may be coated as a powder by dusting or from an aqueous solution. Water soluble compounds would not, however, be suitable as lubricants for surgical sutures due to the nature of surgical procedures. Thus, the lubricant powders would be dissolved prematurely.

U.S. Pat. No. 4,201,216, issued May 6, 1980, to Frank V. Mattei, discloses as a coating for sutures, particularly synthetic absorbable multifilament sutures, an absorbable composition comprising a film-forming polymer and a substantially water-insoluble salt of a C_6 or a higher fatty acid. The coating is preferably applied to the suture from a solvent solution to provide a final coating add-on of from about 2 to 10 percent by weight of the sutures. In accordance with the teachings of said U.S. Pat. No. 4,201,216, the film-forming polymer is preferably a copolymer of lactide and glycolide, while the fatty acid salt is preferably a calcium salt of a C_6 to C_{22} fatty acid. The ratio of polymer to fatty acid salt in the coating composition may be within the range of about 1:4 to 4:1 parts by weight. The coating is wholly absorbable and is particularly useful for improving the dry and wet tie-down smoothness of braided sutures prepared from homopolymers and copolymers of lactide and glycolide, and other absorbable polymers. The patent discloses that where the compositions of the suture and the film former are identical, and in other instances where the suture material may be subject to some surface dissolution and/or surface swelling or softening by reason of the action of the film former solvent thereon, there may be a gradual transition between the substrate composition and the coating composition rather than a sharp interface between them. There may also be some weakening of the suture accompanying the application of such coating compositions.

It is an object of this invention to provide an improved method for coating monofilament sutures, as

well as multi-filament sutures of braided, twisted or covered construction, with a coating that improves the tie-down properties of such monofilament or multifilament sutures. It is a further object of this invention to provide a wholly absorbable coated synthetic monofilament or multifilament suture having improved and substantially equal dry and wet knot tie-down properties. It is yet a further object of this invention to provide such a wholly absorbable coated synthetic monofilament or multifilament suture having improved tie-down properties at least as desirable as those of sutures prepared in accordance with the teaching of U.S. Pat. No. 4,201,216, but having a substantially lower coating weight than that of the sutures of said U.S. Pat. No. 4,201,216, thus tie-down is improved by the minimal application of a safe material, such application being accomplished without using any organic solvents. The appearance and other esthetic attributes of the suture are only minimally affected, if at all, by the low level of add-on of the dry lubricating composition of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the invention, there is provided as a coating for surgical filaments such as sutures, and ligatures, particularly synthetic absorbable monofilament surgical filaments, an absorbable composition comprising a dry, finely powdered, substantially water insoluble salt of a C_6 or higher fatty acid. The coating may be applied on continuous lengths of monofilament or braid, using a series of powdered soft brushes followed by clean, soft wiping brushes to remove excess coating powder, or using other powder coating techniques that are known to the art, to provide a final coating add-on of below about 0.25 percent, and preferably below about 0.15 percent, by weight of the filament. The coating may also be applied to the filament manually by pulling the filament through fingers that had been powdered with the coating salt, e.g., calcium stearate, followed by pulling several times through clean fingers to remove any visible signs of the coating powder.

The fatty acid salt is preferably a calcium salt of a C_6 to C_{22} fatty acid. The coating is particularly useful for improving the dry and wet tie-down smoothness of monofilament sutures, such as those prepared from homopolymers and copolymers of p-dioxanone, polyolefins such as polypropylene, certain polyesters, and the like, as well as braided sutures prepared from homopolymers and copolymers of lactide or glycolide and other absorbable polymers, polyethylene terephthalate, silk, and the like.

The fatty acid salts useful in the coating powder compositions of the invention include the calcium, magnesium, barium, aluminum, and zinc salts of C_6 and higher fatty acids, particularly those having from about 12 to 22 carbon atoms, and mixtures thereof. The calcium salts of stearic, palmitic and oleic acids are particularly preferred for use in the invention. Mixtures of these salts may offer advantages in certain applications.

The amount of coating composition applied to the suture, or the coating add-on, will vary depending upon the construction of the suture, e.g., the number of filaments and tightness of braid or twist. In general, the coating composition applied to a suture will constitute up to about 0.25 percent by weight of the coated suture, and preferably up to about 0.15 percent by weight of the suture. As a practical matter, and for reasons of economy and general performance, it is generally preferred to apply the minimum amount of coating composition consistent with good tie-down performance, and this level of add-on is readily determined experimentally for any particular suture-coating system. Usually, the add-on will be at least about 0.02 weight percent, based on suture weight.

The improvement in tie-down properties imparted to sutures and ligatures may be determined semiquantitatively and subjectively by comparing the tie-down smoothness of coated and uncoated filaments during the act of tying down a single throw knot. Such comparisons are preferably made on both wet and dry filaments since many filaments materials have different tie-down properties when tested wet or dry. Tie-down roughness is graded from 0 to 10, with 0 being comparable to a rough filament and 10 indicating no detectable roughness.

Tie-down properties are evaluated dry after the strands of suture or ligature have been conditioned for at least 2 days in a vacuum drying oven at room temperature and 100 microns absolute pressure, and wet after being immersed in water at 25° C. for 1 minute. Values above 4 are considered acceptable, while values of 7 or higher are comparable to conventional silicone coated silk and are considered fully satisfactory.

The tie-down roughness test is carried out as follows:

The calibration standards for the test are uncoated poly(glycolide-co-lactide) braid, size 2/0, which is arbitrarily assigned a 0 rating, and size 2/0 braided poly(ethylene terephthalate) having a coating of polytetrafluoroethylene, which is assigned a 10 rating. A 24–36 inch strand of the material being tested is looped under a stationary bar, and a single throw know (overhand knot) is formed between the two free ends, near the ends. The two ends are grasped firmly in the hands and the ends are arranged so that the knot has its loops evenly spread out. Using 1–2 pounds of tension, the knot is caused to slide down at a moderate rate, with an even pull, until it comes to rest on the bar. After calibrating the strands for some 10–15 minutes with the two standards, the smoothness of tie-down is judged for the test samples, using the 0–10 scale. Usually, some 3–5 tie-downs are done on each strand, and about 4 strands are done per sample. For wet tie-down, the test is carried out immediately upon removal from the water. Only about 3 to 4 wet tie-downs are done on each strand, since the strand begins to dry out immediately upon removal from the water, and after 3 or 4 tests, is no longer wet. An average is taken of all the evaluations. While the test is subjective, and obviously operator-dependent, experiences has shown that different persons carrying out the test will get about the same results (i.e., the trends and differences between samples will be the same), even though the specific numbers obtained may not be exactly the same.

The following examples are provided to further illustrate and demonstrate the method and product of the invention. Unless otherwise stated, all parts and percentages are by weight.

EXAMPLE 1

Dry, powdered (100 percent smaller than 21 microns, 50 percent smaller than 8.5 microns) calcium stearate (in the form of a commercial food grade product consisting of about $\frac{1}{3}$ C_{16} and $\frac{2}{3}$ C_{18} fatty acid, with small amounts of C_{14} and C_{22} fatty acids) was applied as follows to size

1 dyed poly-p-dioxanone monofilament which had been scoured in acetone for three hours and then dried. The operator's fingers were powdered with the calcium stearate and the strands then individually pulled through the fingers 4–8 times so as to obtain a thorough and intimate coating. After removing the stearate from the fingers, the strands were pulled through clean fingers several more times to remove any visible signs of stearate.

EXAMPLE 2

The foregoing procedure was repeated using the monofilaments and fatty acid salt coating powders identified in Table I. The tie-down properties of the strands were then evaluated using the heretofore described semi-quantitative smoothness-of-tie-down tests, with the results set forth in Table I. The sterilized samples were sterilized either by ethylene oxide (EO) or by gamma irradiation from a cobalt-60 source.

TABLE I

Monofilament		% Add-on, 10 six foot strands	Smoothness of Tie-Down Ratings Based on 0–10 Subjective Scale					
			Dry			Wet		
			Unsterilized/Sterilized			Unsterilized/Sterilized		
Size 0, dyed poly-p-dioxanone monofilament	Uncoated control		3.5	4	(EO)	7.5	7.5	(EO)
Size 0, dyed poly-p-dioxanone monofilament	Calcium stearate	0.041	10	10	"	10	10	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium palmitate		10	9.5	"	9.5	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium laurate		10	10	"	10	10	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium oleate		3	3	"	8	8	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium undecylenate		10	10	"	9.5	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Zinc stearate	0.15	9	9.5	"	9.5	9	"
Size 0, dyed poly-p-dioxanone monofilament	Magnesium stearate		10	10	"	9	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Magnesium myristate		9.5	9.5	"	9.5	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Zinc undecylate		10	10	"	9.5	10	"
Size 0, dyed poly[tetramethylene terephthalate-CO—(2-octadecenyl) succinate] monofilament (U.S. Pat. No. 4,388,296)	Uncoated control		2	1.5	(COBALT)	2	2	(COBALT)
	Calcium stearate		9	8	"	9	9	"
	Calcium palmitate		8	8	"	9	8.5	"
	Calcium laurate		6	5.5	"	2.5	4	"
	Zinc stearate		8.5	8.5	"	8.5	9	"
Size 0 Dyed Polypropylene monofilament	Uncoated control		2	1.5	(EO)	2	2	(EO)
Size 0 Dyed Polypropylene monofilament	Calcium stearate	0.06	9	9	"	9.5	9.5	"
Size 0 Dyed Polypropylene monofilament	Calcium palmitate		9	9	"	9	9	"
Size 0 Dyed Polypropylene monofilament	Calcium laurate		9.5	9.5	"	9.5	9	"
Size 0 Dyed Polypropylene monofilament	Zinc stearate	0.126	9.5	9.5	"	9	9	"
Size 2/0 scoured nylon[1] monofilament	Uncoated Control		6.5	—		7	—	
	Calcium stearate	—	10	—		9.5	—	

[1]Soaked in acetone for 3 hours at room temperature.

As is apparent from the above results, the dry coating of the invention is effective for improving the tie-down characteristics of a variety of surgical filaments such as sutures and ligatures using various salts of fatty acids. In the tests reported in Table I, only the calcium oleate coating of the poly-(p-dioxanone) monofilament suture showed no improvement in the dry test. Even this suture showed slight improvement in the wet tie-down test, although the results were not as good as for the other salts.

It may be readily appreciated that the coating may be used with good results on absorbable monofilament and multifilament sutures and ligatures as well as on nonabsorbable monofilament and multifilament sutures and ligatures.

Nonabsorbable sutures and ligatures such as cotton, linen, silk, polypropylene, and polyester are sometimes coated with nonabsorbable compositions. Polyolefins are usually of monofilament construction while cotton, linen, silk, and polyester are usually of braided, twisted, or covered multifilament construction. While there is usually no requirement that coatings on such sutures be absorbable, the composition of the invention may, nevertheless, be used as a finish for nonabsorbable sutures if desired. The only suture material that has been tried and found not to be improved by the invention is unscoured nylon monofilament. That is because unscoured nylon already has such good tie-down properties that any improvement that might be imparted by the invention is not detectable by the semi-quantitative subjective test used.

EXAMPLE 3

Twenty strands of size 0 undyed polyester (polyethylene terephthalate) braid, in three-foot lengths, were coated with dry calcium stearate powder by the procedure described in Example 1, above. The add-on level for the twenty strands was 1.5 weight percent (this was probably much higher than the add-on would be in a

commercial process, with a more efficient cleaning operation after the coating). Wet tie-down was 8½ (average of 4 strands), while the dry tie-down was 9 (average of 4 strands), using the same test for smoothness of tie-down described above. The uncoated controls were rated at 1 for both dry and wet. The appearance of the coated strands was excellent; they appeared to the naked eye to be uncoated.

What is claimed is:

1. A synthetic surgical filament having improved and substantially equal dry and wet tie-down properties, said surgical filament having been coated with from about 0.02 to 0.25 percent by weight of a composition consisting essentially of a dry, powdered, substantially water-insoluble, absorbable salt of a C_6 or higher fatty acid.

2. A surgical filament of claim 1, wherein said higher fatty acid is selected from the group consisting of C_{12} to C_{22} fatty acids and mixtures thereof.

3. A surgical filament of claim 1, wherein the fatty acid salt is a salt of calcium, magnesium, barium, aluminum, or zinc.

4. A surgical filament of claim 2, wherein the fatty acid salt is a salt of calcium or magnesium.

5. A surgical filament of claim 4, wherein the fatty acid comprises a mixture of stearic and palmitic acid.

6. A surgical filament of claim 5, wherein the fatty acid salt comprises a mixture of calcium palmitate and calcium stearate.

7. A surgical filament of claim 1, coated with from about 0.02 to 0.15 percent of the said mixture.

8. A surgical filament of claim 1, which is comprised of homopolymers or copolymers of lactide or glycolide.

9. A surgical filament of claim 8, wherein said surgical filament is comprised of a copolymer of 10 weight percent lactide and 90 weight percent glycolide.

10. A surgical filament of claim 9, which is a braided multifilament suture or ligature.

11. A surgical filament of claim 1, which comprises a homopolymer or a copolymer of p-dioxanone.

12. A surgical filament of claim 1, which is a monofilament suture or ligature.

13. A surgical filament of claim 11, which is a monofilament suture or ligature.

14. A surgical filament of claim 1 which is composed of a polymer selected from the group consisting of the polyolefins and the polyesters.

15. A method for imparting improving and substantially equal dry and wet tiedown properties to a surgical filament which comprises applying to the surface of said surgical filament in the form of a dry powder a water-insoluble, absorbable salt of a C_6 or higher fatty acid, and thereafter removing from the surface of said surgical filament excess said powder by rubbing said surface in intimate contact with a relatively powder free, nonabrasive surface until no powder is visible to the naked eye on said surgical filament surface.

16. The method of claim 15, wherein the fatty acid salt is the salt of calcium, magnesium, barium, aluminum, or zinc.

17. The method of claim 16, wherein said higher fatty acid is selected from the group consisting of C_{12} to C_{22} fatty acids and mixtures thereof.

18. The method of claim 15, wherein said surgical filament is an absorbable synthetic polymer selected from the group consisting of homopolymers and copolymers of lactide or glycolide.

19. The method of claim 15, wherein said surgical filament is a nonabsorbable synthetic polymer selected from the group consisting of the polyolefins and the polyesters.

20. The method of claim 16 wherein said surgical filament is a homopolymer or a copolymer of p-dioxanone.

* * * * *

EXHIBIT 24

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	)	Civil Action No. 04-12457 PBS

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

HIGHLY CONFIDENTIAL

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
11th January 2006

goes to a line yarn?
A It takes off any excess coating.
Q After that?
A Yes.
Q Now, the oven process that we have here, I think you referred to it as drying and the curing?
A That's correct.
Q Is the drying process here a technical curing process, or is it just drying the yarn?
MR. TAMBURO: Object to the form of the question.
A It does.
MR. BONELLA: What do you mean by that?
A Well, it is actually acting as a -- it dries out the coating, it burns off any excess chemicals as it comes through the bath, and it acts as actually purifies the new coating.
Q Purifies it? What do you mean by that?
A Without speculation, I would just imagine it is -- fills in any gaps and makes sure it is completely covered.
Q Is there material change that takes place during the -- is there any change that takes place on the coating during the drying process?
MR. TAMBURO: Objection to the form of the

EXHIBIT 25

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF ROBERT T. BURKS, M.D.

1. I am an orthopaedic surgeon with the University of Utah Orthopaedic Center. My office is at 590 Wakara Way, Salt Lake City, Utah 84108. I have been practicing for more than 23 years.

2. I received my M.D. from St. Louis University in 1974. I completed a residency in Orthopaedics at the University of California at San Diego in 1983. I completed a knee and sports medicine fellowship at Kaiser Permanente Hospital in San Diego in 1983, and sabbatical at Steadman Hawkins in Vail, Colorado in 1995

3. I am a Professor and Mary Scowcroft Peery Presidential Endowed Chair at the University of Utah Health Sciences Center. I am also the Director of Sports Medicine and Head Physician at the University of Utah. My curriculum vitae are attached as Exhibit 1.

4. My specialties include arthroscopy of the shoulder, knee and ankle, and ligament reconstruction. My research interests include patella stability, cartilage defects, tendon healing to bone.

5. I have reviewed Dr. Fenton's report and I understand he may provide testimony on certain subjects including human anatomy, surgical techniques and surgical devices. I may also provide testimony on these same subjects.

6. I may describe the characteristics of a surgical suture that are generally important to an orthopaedic surgeon. I may also describe the specific features of FiberWire that I find beneficial in my practice.

7. I have been using FiberWire suture in my surgical procedures since 2001. Most of my subjective use of FiberWire occurs during surgery and in the surgical environment, FiberWire is generally wet.

8. Sometime in February 2006, I was contacted by attorneys for Arthrex, Inc. and asked to conduct a tactile feel analysis as well as a knot tie-down analysis of coated and uncoated FiberWire suture. I agreed to conduct the analysis.

9. In March 2006, I received two samples of suture labeled "suture A" and "suture B." Each sample was on a spool and was approximately 3 meters in length. I was told by Arthrex's attorneys that one sample was coated US No. 2 FiberWire and that the other sample was uncoated US No. 2 FiberWire, however, I was not told which sample was coated and which was uncoated.

10. I took the sutures and cut them into some lengths that are appropriate for intraoperative tying and for intraoperative knot tying done arthroscopically. This allowed 5 strands from each spool.

11. I conducted a tactile feel analysis of both suture samples ("suture A" and "suture B"). During the analysis, I noticed that the sample labeled "suture A" generally felt smoother than "suture B." The difference between the two samples was even more pronounced when they were wet, which is how I am most accustomed to using FiberWire.

12. I also conducted a knot tie-down analysis on the two suture samples. I tied several surgeons knots and found that the knots slid easier on the sample labeled "suture A" as compared with the sample labeled "suture B." I felt less friction when sliding the knot on the sample labeled "suture A" as compared with the sample labeled "suture B." Here again, the difference between the two samples was most noticeable when they were wet, as I am accustomed to using FiberWire.

13. After conducting my analysis, I was informed that "suture A" was the coated FiberWire and "suture B" was the uncoated FiberWire.

14. If asked to testify at trial, I may use physical exhibits, as well as other demonstrative exhibits, which have not yet been developed.

15. Within the past four years, I have testified as an expert at deposition in connection with one other case: Philip D. Ceriani, M.D. v. Lonnie Paulos, M.D., and Simon Finger, M.D., et al, Case #: 030906702 (Civil 3rd District Court, Salt Lake City).

16. I am being compensated at a rate of $400 per hour.

Dated: March 24, 2006

Robert T. Burks, M.D.

EXHIBIT 26

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-O-

DEPUY MITEK, INC., a Massachusetts Corporation,	:	Civil Action No.
Plaintiff,	:	04-12457 PBS
-vs-	:	
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LTD., a Private Limited Company of the United Kingdom,	:	EXPERT DEPOSITION OF:
	:	ROBERT T. BURKS, M.D.
Defendants.	:	

-O-

Location: Mariott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

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1 court reporter can transcribe them as opposed to
2 shaking your head or nodding your head; do you
3 understand that?
4 A. Yes.
5 Q. Also, if you'll allow me to finish the
6 question before you answer, it will make for a better
7 transcript. Even though you may even be able to
8 anticipate the end of my question by what I say in the
9 beginning, if you'd allow me to finish and then answer
10 it will allow the reporter to make a clear transcript;
11 do you understand that?
12 A. I do.
13 Q. Also, if I ask you a question and you
14 don't understand, I'll ask that you tell me you don't
15 understand the question. Otherwise, I'll assume that
16 you did understand the question; is that fair?
17 A. Fair.
18 Q. Are you being represented today by
19 counsel?
20 A. Yes.
21 Q. Who is your counsel?
22 A. Sal Tamburo.
23 Q. Do you know when Sal or the law firm
24 Dickstein Shapiro Morin & Oshinsky began representing
25 you for purposes of this case?

7

1 A. In February.
2 Q. Is that when Arthrex or Dickstein
3 contacted you with respect to your role in this case?
4 A. Yes.
5 Q. Are you being compensated for the time you
6 spend on this lawsuit?
7 A. Yes.
8 Q. How are you being compensated?
9 A. How much?
10 Q. Yes.
11 A. $400 an hour.
12 Q. Was that a negotiated fee or was that your
13 standard fee for doing expert consulting?
14 A. I don't really have a standard fee, so I
15 guess you could call it negotiated.
16 Q. Other than money, is there any other
17 compensation you are receiving for work on this case?
18 A. No.
19 Q. Were you given any dollar amount that you
20 should not exceed in performing work for Arthrex in
21 this case?
22 A. No.
23 Q. I'm going to hand you DePuy Mitek Exhibit
24 231 and ask you if you recognize this document,
25 Exhibit 231?

8

1 A. Yes.
2 Q. What is Exhibit Number 231?
3 A. A subpoena for me.
4 Q. Did you understand that be Exhibit 231 was
5 a subpoena on you for certain documents and things
6 listed in schedule A of Exhibit 231?
7 A. Yes.
8 Q. Today are you producing any documents or
9 things in response to the subpoena, Exhibit 231?
10 A. No.
11 Q. If you could turn to page two of Exhibit
12 Number 231, please. Do you see request number one for
13 documents there, being all communications between any
14 of Arthrex, you, Dr. Mukherjee and Dickstein Shapiro
15 Morin & Oshinsky concerning the lawsuit commenced by
16 the plaintiff attached as Exhibit 1?
17 A. Yes.
18 Q. Did you perform any search that might be
19 responsive to request number one in Exhibit Number
20 231?
21 A. Yes.
22 Q. Did you find any?
23 A. No.
24 Q. Request number two in Exhibit 231 is all
25 documents concerning this lawsuit, including, but not

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1 limited -- well, hold on. Strike that.
2 Did you perform a reasonable search for
3 documents in response to request number two in
4 Schedule A of Exhibit 231?
5 A. I guess I don't see the difference. There
6 aren't any documents that I'm aware of in the lawsuit.
7 Q. Under things to be produced on page two of
8 Exhibit Number 231, request number one is all tested
9 and untested samples referred to in Expert Report of
10 Robert T. Burks, MD dated March 24, 2006, including,
11 but not limited to suture A and suture B. Do you see
12 that?
13 A. I do.
14 Q. Did you perform a search for things
15 responsive to request number one?
16 A. No.
17 Q. You did not?
18 A. I knew it didn't exist.
19 Q. You knew what didn't exist?
20 A. The suture.
21 Q. You mean the tested and untested samples?
22 A. The pieces that I had I had disposed of
23 when I was done. I knew there wasn't anything to look
24 for.
25 Q. Under request number two on things to be

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1 produced on page two of Exhibit 231 is all equipment
2 used to test the samples as described in paragraphs
3 nine through 13 of Expert Report of Robert T. Burks,
4 MD dated March 24, 2006, including, but not limited to
5 the equipment that was used to cut and wet the samples
6 and to conduct the tactile feel analysis and knot
7 tie-down analysis; do you see that?
8 A. I do.
9 Q. Did you perform a search for the materials
10 requested in request number 2?
11 A. No.
12 Q. Why not?
13 A. The equipment that was used was a pair of
14 scissors just to cut it, something from home, I felt
15 like it didn't have relevance.
16 Q. What about the solution that was used to
17 wet these tested samples?
18 A. I used tap water.
19 Q. Did you use anything else in performing
20 the tests described in paragraphs nine through 13 of
21 your expert report other than tap water and scissors
22 and the sutures?
23 MR. TAMBURO: It might help if the witness
24 had his report in front of him to refer to.
25 A. The things used, like a pair of gloves,

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1 are disposed of after and they're just a generic set.
2 There wasn't anything used that would be unique that I
3 felt would be worthwhile to produce.
4 Q. So you used gloves when you performed the
5 tactile feel analysis and knot tie-down analysis?
6 A. I did both. I used and didn't use gloves.
7 Q. Is there any reason why you decided not to
8 bring gloves today?
9 A. No.
10 Q. Did your counsel advise you to bring
11 gloves?
12 A. No.
13 Q. Did you go over -- did you have a chance
14 to go over Exhibit 231 with your counsel before coming
15 to today's deposition?
16 A. Yes, we looked at it.
17 Q. Dr. Burks, could you please describe your
18 formal education post-high school for me, please.
19 A. I did medical school at St. Louis
20 university. I guess after high school I did college
21 at Southern Methodist University, medical school at
22 St. Louis university, orthopedic training at
23 University of California San Diego.
24 Q. When did you graduate from undergrad?
25 A. Undergrad college was '74.

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1 Q. What about medical school?
2 A. '78.
3 Q. Then, after medical school, where did you
4 go?
5 A. To residency training.
6 Q. When did you finish your residency
7 training?
8 A. '83.
9 Q. Where was your residency training?
10 A. University of California San Diego.
11 Q. Did you have a specialty there?
12 A. Yes. Well, there's no specialty in
13 training per se, but I did do a fellowship during that
14 time with Dale Daniel at Kaiser Permanente.
15 Q. What was that fellowship in?
16 A. Knee and sports medicine.
17 Q. When did you finish your fellowship in
18 knee and sports medicine?
19 A. '83.
20 Q. Other than those programs or degrees you
21 mentioned, are there any other -- is there any other
22 formal education that you've gone through?
23 A. No.
24 Q. Once you completed your fellowship in knee
25 and sports medicine in 1983, what did you do?

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1 A. I went into private practice in St. Louis,
2 Missouri.
3 Q. What was the focus of your private
4 practice in St. Louis?
5 A. Sports medicine, general orthopedics.
6 Q. Did you focus on any particular parts of
7 the body within sports medicine and general
8 orthopedics?
9 A. Knee and shoulder were the big focus.
10 Q. And when did you leave private practice in
11 St. Louis?
12 A. I was there three years; I believe it was
13 '86.
14 Q. Then what did you do in 1986?
15 A. I went to Wayne State University in
16 Detroit.
17 Q. What did you do at Wayne State?
18 A. I was on the academic staff there and was
19 the head of sports medicine.
20 Q. Your time spent at Wayne State, was that
21 strictly in an academic environment or did that also
22 include a clinical practice?
23 A. Yes. I mean, it was a clinical practice,
24 but it was as a full-time faculty member.
25 Q. Can you explain how that works, your role

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at Wayne State, how it was spent between full-time faculty member and participating in a clinical practice?

A. Well, there's really no distinction. I mean, my job was to take care of patients and people. And so the education was for residents and that's what they were training to do was take care of people.

So there really wasn't a distinction between a clinical practice and what you are doing academically as far as your work goes.

Q. So did you teach in a classroom setting?

A. No.

Q. So I think I understand. What type of medicine did you practice at Wayne State as a full-time faculty member and in a clinical practice?

A. It was orthopedic surgery with an emphasis in sports medicine.

Q. Again, did you focus on the knee and shoulder areas?

A. Yes.

Q. When you were at Wayne State what were the -- generally what were the procedures that you would perform for shoulder surgeries?

A. Perform shoulder instability operations, rotator cuff operations, things that we do for what we

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call impingement, shoulder pain procedures, procedures that revolve around the clavicle.

Q. Anything else you can think of?

A. I mean, it's a pretty wide area, but those are the main things.

Q. What about when you were at Wayne State, what were the procedures that you would perform for knee surgeries?

A. Ligament reconstructions, operations for instability of the knee cap, cartilage procedures, meniscus procedures.

Q. When you were at Wayne State, did you perform any ankle surgeries?

A. Sure.

Q. What ankle surgeries? What procedures would you perform doing ankle surgeries?

A. The main procedures revolved around arthroscopy, and then I would do some procedures that revolved around loose ankle joints where people have chronic ankle sprains and tightening those up.

Q. Then, I take it, at some point you left Wayne State?

A. Correct.

Q. What year was that?

A. '88.

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Q. In 1988 after leaving Wayne State, what did you do?

A. I came here to the University of Utah.

Q. What position did you enter the University of Utah in 1988?

A. I was an assistant professor in orthopedic surgery. And we didn't really have a true division, but I was part of the sports medicine team.

Q. Can you generally describe your duties as an assistant professor in the orthopedic surgery department at the University of Utah?

A. Duties were to take care of standard patients that we would see, to instruct residents in clinical evaluation of patients and surgical treatment of patients, to be involved in some areas of research and produce academically, and were involved with taking care of the athletic teams.

Q. While at the University of Utah, I take it from 1988 to the present you've remained at the University of Utah?

A. Yes.

Q. From 1988 to the present, do you perform any classroom teaching?

A. Minimally. Occasionally it comes up, but not very much.

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Q. What classes would you teach when it comes up?

A. It's usually just an isolated lecture, not like a class series. So it would be lectures to the residents or to medical students on a specific topic, sometimes to physical therapy students.

Q. Since 1988, how have your duties and responsibilities at the University of Utah changed?

A. I don't think they've changed much.

Q. Okay. At some point you did become head of the sports medicine division, though, right?

A. Correct.

Q. Do you know when that happened?

A. I'd be guessing a little. I'm not sure of the exact year.

Q. How about 1992, does that sound familiar?

A. That's probably close.

Q. Dr. Burks, I'm going to hand you Exhibit Number 233. This is a printout of a web page from the University of Utah. If you could just please look at that.

MR. TAMBURO: Do you have another copy?

Q. No. Just let me know if that's generally accurate.

A. Yes.

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Q. Dr. Burks, can you describe for me your relationship with Arthrex, Inc.?
MR. TAMBURO: Objection, vague.
A. I am a consumer. Over the years I have been an advisor for different products. That's it.
Q. You say you are a consumer of Arthrex products. What Arthrex products do you use?
A. Well, we use things like drill guides, use suture anchors and sutures, drill bits. That's it.
Q. Do you use any Arthrex knee fixation devices?
A. I have used Arthrex knee fixation devices but don't currently use any.
Q. What did you use?
A. They have an interference screw that is metal and one that is absorbable that I used to use that I don't use now.
Q. Earlier you said things like we used things like drill guides, suture anchors, and sutures, drill bits. Who were you referring to when you said "we"?
A. I guess it was the generic "we" of the sports medicine service.
Q. Do you personally use those Arthrex products?

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A. Oh, yes.
Q. Do you have any consulting agreements with Arthrex?
A. To be honest, I'm not sure of the direct answer to give you on that. I have a couple of pieces of equipment that I have worked with them on in developing, so that might be considered a consulting agreement.
I'm not a consultant, just a generic like on a board of advisors or something like that.
Q. I don't understand when you say "I have a couple of pieces I equipment I worked with them on in developing so that might be considered a consulting agreement", could you explain that?
A. Well, I went to them to develop a guide for a knee ligament reconstruction. They liked the idea. They made the guide. They have the guide as one of the products that they sell, and then I get some royalty from their sales.
Q. Okay. So other than services you performed for this case, have you received money from Arthrex for other services such as, for example, this work you did with the guide?
A. I think I just said I get royalties for that.

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Q. Other than royalties and other than money for your work you've performed in this lawsuit, do you receive any other money from Arthrex?
A. No.
Q. How many different pieces of Arthrex equipment to you receive royalties on?
A. There is a knee ligament guide system that has a few different pieces in it. So I can't give an exact number. It's sort of a guide system with four or five different pieces, parts of it.
There is a screw that we use for augmenting ligament fixation that I get some royalties on along with those guides.
Q. Do you know what the trade name is for the knee ligament guides that you receive royalties from Arthrex on?
A. It's kind of silly that I wouldn't be able to give you that. It's for posterior cruciate ligament reconstruction.
Q. And do you know what the trade name is on the screw that you receive royalties from Arthrex on?
A. I don't.
Q. For what area of the body is this screw used on?
A. It could be used anywhere, but I think the

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large majority would be at the knee.
Q. Are you the named inventor on any patents?
A. No.
Q. The screw that you developed with Arthrex, is that used for the ACL or PCL?
A. Can be either.
Q. Is that an interference screw?
A. No. It's a screw we typically refer to as a post. And what that means is that suture from a ligament or tendon gets tied around this to help hold it while it's healing in.
Q. You also said, in describing your relationship with Arthrex, you used the word "advisor". We've just been talking about you developing certain equipment. Is that what you meant by advisor?
A. Yes.
Q. Do you advise Arthrex in any other way other than what we've just talked about with respect to developing equipment?
A. No.
Q. Do you know Dr. Paul Fenton from Toledo, Ohio?
A. I don't.
Q. What about Dr. Marlow Goebel?

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A. Poor wording. I guess it was to say that my sense of how FiberWire works and handles, that subjective feel of that is in that environment.
Q. So you don't use FiberWire in any non-surgical environment, do you?
A. Well, I've used FiberWire in laboratory studies when we do cadaveric studies or other things. But I don't use it for non-medically related things.
Q. When you say "most of my subjective use of FiberWire occurs during surgery", were you referring to the surgical environment versus non-surgical environment like you just described?
A. Right.
Q. Then you say "FiberWire is generally wet in the surgical environment", what does that mean?
A. Well, in the environment where I work arthroscopically we work with fluids, so it's hard for a suture not to be wet.
Obviously, there are times where we work in a dry air environment and the suture may get wet passing through tissue, but it's not necessarily intentionally wetted like it is with arthroscopy.
Q. During surgery, do you wet FiberWire before is it's introduced into the body?
A. Not deliberately, no.

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Q. Earlier you said the suture may get wet passing through tissue, but it's not necessarily intentionally like it is with arthroscopy. I don't know what that means.
A. In an arthroscopic environment we have a microscope in a joint and we distend the joint so we can see with fluid.
So any time we introduce suture into that environment it's under water, if you will. So no matter what we do with it, by the time we start to use it, it's wet.
Q. When using FiberWire in a surgical environment, do you always wear gloves?
A. Yes.
Q. What about in the -- let me rephrase the question. In a nonsurgical environment, do you always wear gloves when using FiberWire?
A. No.
Q. What determines whether you wear gloves?
A. Either sterility for a patient or protection for myself.
Q. If it's a nonsurgical environment, how does sterility of the patient matter?
A. It doesn't.
Q. In a nonsurgical environment, what

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determines whether you wear gloves?
A. In a nonsurgical environment it would be protection for me.
Q. Okay. Protection from what?
A. Well, if we do cadaveric surgery some cadavers have diseases so we may want to have gloves on when we work with them.
Q. What about in the laboratory environment, when you are using FiberWire, do you wear gloves?
A. I guess it depends on what you mean by the laboratory environment.
Q. By laboratory environment, I mean anything other than a surgical or nonsurgical environment like we've been talking about.
A. Well, we do, for example, cadaveric surgery in the laboratory, so we would consider that a laboratory environment, and I would use gloves for self-protection in that setting.
Q. Let me ask you a better question. Outside of a surgical environment or nonsurgical environment, do you wear gloves when using FiberWire?
A. I guess I would say no.
Q. Dr. Burks, if you could turn in Exhibit 232 to paragraph eight, you state: "Sometime in February 2006 I was contacted by attorneys for

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Arthrex, Inc., and asked to conduct a tactile feel analysis as well as a knot tie-down analysis of coated and uncoated FiberWire suture. I agreed to conduct the analysis." Do you see that?
A. I do.
Q. Who contacted you in February of 2006?
A. Sal Tamburo.
Q. Anyone else?
A. No.
Q. Do you remember the substance of the conversation you had with Sal in February of 2006?
A. Yes.
Q. What was that substance?
A. He said that Arthrex and more, in particular, FiberWire was involved in a patent infringement lawsuit and he was wondering, since I've had experience of using FiberWire, if I would be willing to talk about FiberWire and how its used, etc., and if I'd be willing to look at FiberWire in a couple of different states and give him feedback on what I thought about that.
Q. What were those couple different states?
A. My understanding was that it was a coated suture and a not-coated suture.
Q. Anything else?

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A. I'll try to clarify again. I didn't, in my mind, view it as a pure test A/test B. So when you handle suture tying knots and doing things with it, you have a tactile feel. So I didn't -- so that's part of the knot tying. So I didn't segregate it out as two isolated separate things.
Q. So in your report, Exhibit 232, are you making two conclusions based on a conclusion of the tactile feel analysis and a conclusion based on the knot tie-down analysis?
A. I'll try to clarify again. A knot tie-down analysis I view as having a tactile aspect to it as well, you are feeling the suture as you tie it. So I don't view them as totally isolated.
Q. Okay. So how many analyses did you perform as reflected in Exhibit 232?
A. I used all the strands and tied multiple knots on all the strands. So I'm not, I guess, quite sure -- I can't tell you I did 20 knots on each strand or 30, but they were each used for multiple knot tying.
Q. My question might have been unclear. Not how many times did you perform the analysis, but how many different analyses did you do in coming to the conclusions as expressed in Exhibit Number 232?

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MR. TAMBURO: Objection, vague.
A. I felt the suture and I tied knots with the suture.
Q. But earlier you testified that that's all encompassed in the knot tie-down analysis. So I'm wondering did you do a knot tie-down analysis and that's it and that had two subparts or two different analyses and then come up with a conclusion -- come up with two different conclusions?
MR. TAMBURO: Objection, mischaracterizes the testimony.
A. Again, I'm not trying to characterize in this that these are segregated separate tests, but this was a tactile feel and knot tying. It was a length subjective feel on both of those.
So when you tie knots, you get a tactile feel. So I was making the statement that on the tactile feel, how it feels to me, it felt this way and when I tied knots, it also felt that way. It's sometimes hard to do one without doing the other.
Q. When you were doing -- when you did the tactile feel analysis and the knot tie-down analysis as expressed in Exhibit 232 were you wearing gloves?
A. Not always.
Q. Can you explain the breakdown?

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A. I tried to try knots partly with gloves to see if I felt that there was a difference and partly without gloves to see if I could feel a difference.
Q. Did using gloves in the tests in Exhibit 232 affect your ability to distinguish between suture A and suture B?
A. I think, clearly, using gloves makes the feel of the suture a little different. I guess I can't answer directly to say if it makes the difference but, yes, it probably makes a difference.
Q. What difference does it make?
A. You are covering your skin with the gloves, so, you know, as you feel suture, your absolute sensation of the suture probably changes some.
Q. Could you have reached the same conclusions you reached in Exhibit 232 if you solely used gloves in performing the tests?
A. I didn't do it that way, so I guess I can't answer that and say yes or no.
Q. Did not using gloves help you to distinguish between suture A and suture B?
A. Potentially, yes.
Q. Did it or -- I'm asking you if, in fact, it did?

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A. And I'm telling you my answer is it potentially did.
Q. I don't think I understand that. How could it potentially? I mean either it did or didn't, right?
A. No.
MR. TAMBURO: Objection, argumentative.
Q. Why do you say "potentially"?
A. I'm trying to be honest. I did feel without gloves and I know there's a pile A and a pile B, so there is potential that feeling suture without gloves made me feel that A was a little different than B that had I been gloved the entire time, I might not have detected.
Q. So from start to finish then after you cut the suture samples until the time you made your conclusions expressed in Exhibit Number 232, how long was that?
A. I'll give you the same answer: 45 minutes or so.
Q. So the 45 minutes encompassed roughly ten minutes you spent on the tactile feel analysis?
A. No.
Q. So 45 minutes plus ten minutes or just 45 minutes?

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it was my overall take from looking at them.
Q. Do you remember how many -- strike that.
Does a suture that has less friction when sliding that knot mean that the suture has better knot tie-down performance?
A. Not necessarily.
Q. Why?
A. Well, if you envision a perfectly smooth suture, for example, if you slide a knot it might slide very easily but it might also tend to not hold as well because there's not as much inherent friction in it.
Q. Does a smoother suture mean it has better tactile feel than a suture that is not as smooth?
A. I would say no, I don't know that I'd say it's a better tactile feel.
Q. Why did you use a surgeon's knot when you did the knot tie-down analysis in Exhibit 232?
A. I think what I would do is say that -- again, maybe my critique of the verbiage would be at fault. So I guess I wouldn't -- you know, we talked earlier about what a surgeon's knot is.
Q. Uh-huh?
A. And I probably didn't focus on it enough to say that they're not necessarily surgeons' knots as

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I described them.
Q. Okay, so why did you use the particular knots, then, that you used in the knot tie-down analysis?
A. I just tried to reproduce what I do in the operating room.
Q. In paragraph 11 in Exhibit 232 you state that suture A generally felt smoother than suture B. What do you mean by "generally"?
A. The differences between the sutures were subtle. I mean, they were not sharp, distinct. So I'm meaning that in comparing them, my take was that it was generally smoother.
Q. Were there any of the sutures in the tactile feel analysis where you couldn't tell the difference between suture A and suture B?
A. It was not my intent at the time in looking at the sutures to compare each strand side to side. My intent was to look at sort of spool A and spool B. So it was to get a feel of, in general, how do they feel between the two.
So I didn't take a strand and say is this one different? And is this one different? And go down through that five times, because I felt it was all the same suture.

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Q. But were there any where you couldn't tell a difference? I mean, it was pretty close?
A. Sure, it was pretty close.
Q. Let me rephrase. Were there any where you couldn't tell the difference between suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. I don't remember specifically having ones that I would say I clearly feel a difference on this one and I clearly don't on the next one. It was a general feel of all of them.
Q. Dr. Burks, how would you describe your relationship with Ethicon?
A. I guess none.
Q. None? So you would say that you have a closer relationship with Arthrex?
A. Yes.
Q. What about could you describe your relationship with DePuy Mitek?
A. I have been a consultant with DePuy Mitek. Just this week I was helping on an educational course for DePuy Mitek reps. But I've had no product or anything like that with DePuy Mitek.
Q. You mean development product work?

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A. Yes.
Q. What was the educational course this last week that you helped with DePuy Mitek?
A. It was educating reps who go into the operating room and, you know, are helping surgeons with their materials, sutures, implants, what not, and how to handle the operating room environment, be appropriate and be helpful.
Q. The course was not on a particular DePuy Mitek technique or anything like that, it was --
A. It was not focused on a particular product but it was focused on helping reps better sell DePuy Mitek products.
Q. By being more professional in the operating room?
A. Correct.
Q. Is this the first time you have done that for DePuy Mitek?
A. This is the second.
Q. Other than those two courses, have you consulted with DePuy Mitek in any other courses?
A. Yes.
Q. What are those?
A. There was an educational course in Chicago and you are going to say when and I'm going to guess

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four years ago. It was a cadaver course where they were doing DePuy Mitek products and they asked me to come give a couple of talks and help in the lab using those products with the doctors who were there.
Q. Do you remember what those products were?
A. Not specifically. They were suture anchors, suture passing instruments, but I don't remember a specific product.
Q. Are you a consumer of DePuy Mitek products?
A. Sure.
Q. What DePuy Mitek products do you use?
A. Well, I mentioned earlier I use OrthoCord. I use some DePuy Mitek anchors. They make an electric cautery unit that we use, in every case we use electric cautery.
They have some suture-passing instruments that we use. I use one of their drill guides and fixation sets for ACL surgery.
Q. When you do an ACL fixation, what product do you use?
A. It depends on the type of ACL that we're doing. If I use a bone/tendon/bone graft which is a common graft, on the femoral side, I fix it with a DePuy Mitek device which is a couple of absorbable

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pins, and on the tibial side I fix it with either a DePuy Mitek screw or a screw from a different company depending on upon quality.
On the hamstring, I typically on the femoral side use a Smith and Nephew product --
Q. EndoButton?
A. EndoButton. On the tibial side I typically use a Milagro screw and frequently for the post use that Arthrex screw.
Q. When you say hamstring, that's soft tissue?
A. Correct.
Q. Semitendonosis?
A. Very good.
MR. TAMBURO: We're all half doctors here.
MR. FALKE: Let's take a break.
THE VIDEOGRAPHER: Off the record, 5:54.
(Brief recess.)
THE VIDEOGRAPHER: On the record, 6:02.
Q. (By Mr. Falke) Dr. Burks, I'm going to hand you DePuy Mitek Exhibit 286, DePuy Mitek Exhibit 284 and DePuy Mitek 285. These are FiberWire samples that were produced to us from Pearsalls who is a company that makes FiberWire for Arthrex.
I covered up on those exhibits the

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manufacturing state that those sutures have gone through. And I'm wondering if you can look at those, analyze them, do whatever you have to do, but tell me which ones are coated and which ones are not coated, if any?
A. So these are three separate types of suture?
Q. They're three different sutures. Well, I'm going to take that back. I don't know if they're three different sutures.
MR. TAMBURO: You are not sure what they are.
MR. FALKE: We know what they are, yeah. I mean, based on Pearsalls' representations of what they are. If you need to cut them and get you a glass of water, if you want to wet them.
MR. TAMBURO: Are they in the same form in which they were produced?
MR. FALKE: Yes, we did not alter them.
MR. TAMBURO: Do we have Bates numbers?
Q. Slow down. Just for the record, so the record is clear, what did you just do, Dr. Burks?
A. I just opened the suture that was in the bag.
Q. What Exhibit Number is that?

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A. That is 286.
Q. You cut a piece off of the suture in Exhibit 286?
A. Right.
Q. And --
MR. TAMBURO: There's no Bates numbers on these?
MR. FALKE: There were no Bates numbers.
Q. Would you put that on the suture you cut from Exhibit 286 and mark with a pen Exhibit 286. Now, can you explain what you are doing now, Dr. Burks? First, can you put the suture that you took out of 286 back in the bag?
A. (Witness complies.)
Q. Thank you, and then proceed. Can you explain for the record what you are doing now?
A. I'm opening 285.
Q. You are cutting suture sample from Exhibit 285, right?
A. Yes.
Q. Could you please mark with the tape Exhibit 285 that you've cut? Proceed. Can you state what for the record what you are doing now?
A. I'm opening number 284.
Q. And cutting a suture from Exhibit 284?

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A. Yes.
Q. And now you are going to mark the suture sample that you took from Exhibit 284 with a flag?
A. Correct.
Q. Can you hand me the original sample sets back?
A. (Witness complies.)
Q. Also, I'm going to hand you DePuy Mitek Exhibit 234 which is a chart I'd like you to fill out if you could, please, and under the suture column put the numbers corresponding to the suture samples you've just cut, just 284, 285 and 286?
A. Fair enough?
Q. Fair enough.
A. Have we got a while?
Q. However long it takes you.
MR. TAMBURO: Are you representing that one of them is coated, one of them is not coated?
MR. FALKE: I'm not making any representations. They could all be coated, they could all be uncoated, could be a mix?
A. Can I use your notebook?
Q. Of course. What do you need?
A. I was going to use one of those metal rings.

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Q. Sure. First, can you do a tactile feel analysis on it? Can you tell the difference?
A. Kind of -- like I said, when you tie knots you combine that together.
Q. Can you explain what you are doing now?
A. I don't want to knock your little deal off, you know? I'm just getting a sense for how it slides and trying to put down a couple of throws.
Q. Which Exhibit Number are you working on?
A. I'm on 285.
Q. Okay. What type of knots are you throwing?
A. Half hitches.
Q. Now, can you explain what you are doing, Dr. Burks?
A. Same thing.
Q. With which exhibit?
A. 286.
Q. Are you doing the same thing you did with the previous one?
A. Yes.
Q. Same knot configurations?
A. Uh-huh.
Q. Can you tell a difference between the first two sutures, Dr. Burks, Exhibit 285 and --
A. 286.

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Q. And 286? Can you explain for the record please what you are doing now, Dr. Burks?
A. I'm tying 284.
(Discussion off the record.)
A. Okay. So where is my little sheet here?
Q. Based on what you've done so far, Dr. Burks, can you tell any difference between the sutures?
A. I feel like I do feel a difference.
Q. Okay. How would you describe that difference?
A. Well, I would say at the moment 285 seems a little smoother to me than 284. So I would say 285 is coated and 284 isn't coated.
Q. How sure are you of that?
A. I would not put my children's lives on it, but given the subjective feel.
Q. Is it a subtle difference?
A. It's a subtle difference.
Q. Can you explain, Dr. Burks, what you are doing now?
A. Just throwing knots. I would say 286 seems coated as well.
Q. If you had gloves on right now, would that change the confidence level you have in determining

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whether those are coated or uncoated sutures?
MR. TAMBURO: Objection, calls for speculation.
A. I think gloves can make a difference, yeah.
Q. How do they make a difference? The difference between the sutures is more subtle, right, with gloves because you don't have the contact like you described earlier with the skin?
A. Yeah. Again, this is obviously a very subjective feel test. Some of that feel comes from how the suture feels and some of it comes from how you feel when you slide a knot. So we're not talking rocks and water as far as differences and so. . .
Q. How would you qualify the difference that you just observed, based on your test?
A. When you say "qualify" are you asking for like an amount?
Q. How would you characterize the difference between the sutures?
A. Well the difference is, I think, subtle and there's no doubt in my mind that I could line up, you know, a hundred sutures and have error where I would say, you know, I think this one is one way or the other and make a mistake.

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So there's certainly not enough difference to clearly say that I know every time exactly how that feels.
Q. Okay. Could you just initial, please, the chart that you did?
A. This right here?
Q. Yes.
A. Okay.
Q. And put the date.
A. (Witness complies.)
Q. Okay. For the record, I have to mark the exhibits, the sutures that you tied onto my binder. Can you untie those?
A. I can just open the binder.
Q. How confident were you that 286 was coated?
MR. TAMBURO: Objection, vague.
A. I guess I've said that differences are subtle. So I'm going by a subjective feel. So I feel like there's a difference. Am I going to bet a lot of money on it? No, but that's my take.
MR. FALKE: Okay. For the record I'm going to mark the suture that Dr. Burks tested with Exhibit 235 -- I'm going to state that over again.
For the record, I'm going to mark with

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Exhibit 235 the suture Exhibit 284 that Dr. Burks just tested, and I'm going to mark Dr. Burks' tested suture 286 with DePuy Mitek Exhibit 236, and I'm going to mark Dr. Burks' tested suture 285 with DePuy Mitek Exhibit 237.
I have no further questions.
EXAMINATION
BY MR. TAMBURO:
Q. Dr. Burks, there was some discussion about work you had performed on behalf of DePuy Mitek; do you recall that?
A. Yes.
Q. Were you compensated by DePuy Mitek for the work you performed?
A. Yes.
MR. TAMBURO: I have no further questions.
MR. FALKE: Okay, thank you for your time.
THE VIDEOGRAPHER: End of deposition, 6:18.
-O-

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Deponent's Certificate

I, ROBERT T. BURKS, M.D., deponent herein, do hereby certify and declare the within and foregoing transcription to be my deposition in said action taken on June 7, 2006; that I have read, corrected, and do hereby affix my signature to said deposition.

DATED this _____ day of _____, 2006.

_____
Deponent

)
STATE OF UTAH) ss.
)

SUBSCRIBED AND SWORN to before me this _____ day of _____, 2006.

_____
Notary Public residing in
_____

My Commission Expires:

_____

101

Reporter's Certificate

State of Utah)
County of Salt Lake)

I, Denise Kirk, Certified Shorthand Reporter, Registered Professional Reporter, and Notary Public for the State of Utah, do hereby certify:
THAT the foregoing proceedings were taken before me at the time and place set forth herein; that the witness was duly sworn to tell the truth, the whole truth, and nothing but the truth; and that the proceedings were taken down by me in shorthand and thereafter transcribed into typewriting under my direction and supervision;
THAT the foregoing pages contain a true and correct transcription of my said shorthand notes so taken.
IN WITNESS WHEREOF, I have subscribed my name and affixed my seal this 11th day of June, 2006.

_____
DENISE KIRK, CSR/RPR

My commission expires:
August 30, 2006

EXHIBIT 27

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Declaration of Dr. David Brookstein In Support of DePuy Mitek's
Claim Interpretation of the Hunter Patent and Summary Judgment of Infringement

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and conducted research in

23. In my opinion, the "function" of the first fiber-forming material is the same as the function of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**Function of Limitation Under the Doctrine of Equivalents**	**Function of UHMWPE in FiberWire™ and TigerWire™ Suture Products**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The function of the first set of yarns is to contribute a property that is different than a yarn from the second set.	UHMWPE contributes different lubricity and strength properties to the heterogeneous braid than PET.

24. My opinion regarding the "function" of the first fiber-forming material is supported by the '446 Patent. The '446 Patent explains that the first fiber forming material is "dissimilar" to the second fiber and the braid of dissimilar yarns provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. 2 at 2:50-52; 3:43-48). Further, the '446 Patent explains that it is possible to "tailor the physical" properties by "varying the type and proportion of each of the dissimilar fiber forming materials used" (*id*. at 2:58-61). Also, the patent notes that the different fiber components make different relative contributions to one or more properties of the heterogeneous braid (*id*. at 8:19-21).

25. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid.

Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Ex. 5 at 306:17-307:14; Ex. 6; *see also* Ex. 5 at 307:15-308:14; Ex. 7). Further, as I explained in my rebuttal report with respect to Mr. Grafton's work and Arthrex's 234 Patent, FiberWire's PE also provides lubricity and other surface properties that are different than PET, and PET when braided with PE in FiberWire increases the knot holding strength.

26. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Way" of Limitation Under the Doctrine of Equivalents**	**Way UHMWPE performs its Function in FiberWire™ and TigerWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Ex. 8 at 99-107).

27. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct intertwining contact" with a yarn from the second set (Ex. 2 at 2:40-44; *see also* 3:21-28; 3:40-45). The '446 Patent further explains that the heterogeneous braid properties are due to the "mechanical interlocking or weaving of the individual yarns" (*id*. at 2:56-58; 3:43-48). Also, during the

(Ex. 17 at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

47. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. 5 at 119:5-9; Ex. 8 at 94:2-9; Ex. 18 at 48:1-50:16; Ex. 19 at ARM002104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters per minute (Ex. 5 at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. 5 at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. 5 at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. 5 at 95:14-17). The process is then repeated. I have measured

[3] Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DMI Exhibits 284, 342, and 285, Exs. 20, 21, and 22, respectively). I determined that the linear density of DMI Ex. 284 (uncoated) is 2393 denier, DMI Ex. 342 (coated once) is 2474 denier, and DMI Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of DMI Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated DMI Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from DMI Ex. 342. Thus, the total pick-up of Ex. 285 over DMI Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Ex. 15).

48. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire

64. It is my expert opinion and observation that the coating only appears on the surface of the braid.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: September 1, 2006 /s/

EXHIBIT 28

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation Plaintiff	)	
-VS-	)	CA No. 04-12457-PBS Pages 1 - 87
ARTHREX, INC., a Delaware Corporation, et al, Defendant	)	

MARKMAN HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., LYNN A. MALINOSKI, ESQ., and MICHAEL J. BONELLA, ESQ., Woodcock Washburn, One Liberty Place, 47th Floor, Philadelphia, Pennsylvania, 19103, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
September 26, 2006, 2:00 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

the invention that it cannot include bioabsorbable materials."

THE COURT: All right, thank you very much. And you want me to do what now? You want me to -- you think it sort of morphs into the same analysis because as soon as I adopt, if I adopt yours, you say, bang, there's an infringement? Is that all there is to it?

MS. ELDERKIN: Pretty much, your Honor. We have obviously --

THE COURT: And if I say, bang, no, this isn't it, then they win?

MS. ELDERKIN: No. We say, bang, if you go for us, we think there are no disputed issues of fact, and you should grant summary judgment of infringement. But if you were to find for them on either issue, there are genuine issues of material fact about infringement that would preclude summary judgment and would --

THE COURT: Like what? You're talking about equivalents?

MS. ELDERKIN: Yes.

THE COURT: So not to get ahead of ourselves --

MS. ELDERKIN: I'm sorry. Not just equivalents, but also under the "consisting essentially of," whether the coating materially affects the basic and novel characteristics. So even under their definition of what

those basic and novel characteristics are, there's a fact issue under their definition of whether the coating "materially affects" those basic and novel properties.

THE COURT: Just getting to the coating for a minute, though, suppose I went with their view and there was evidence that the coating substantially improves the handleability -- would that be it?

MR. SABER: Handleability.

THE COURT: So you would say, at the very least, that gets a jury claim?

MS. ELDERKIN: Yes, your Honor.

THE COURT: So you would agree with their legal analysis, which is what I was actually struggling with a little bit, which is, if something like a coating materially improves on the invention, then that would qualify as taking you out of infringement?

MS. ELDERKIN: I'm not sure that it would, your Honor, and one of the reasons --

THE COURT: As opposed to detracting or defeating the invention?

MS. ELDERKIN: In this case, I'm not sure that it would because the patent even says you can put a coating on these sutures to enhance the pliability, to enhance the lubricity. I forget the exact term that they use.

THE COURT: Right, I noticed that the coatings were

EXHIBIT 29

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek's Memorandum in Support of Its Motion for Summary Judgment of Infringement and No Inequitable Conduct

DEPUY MITEK'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT

I. INTRODUCTION

Plaintiff, DePuy Mitek, Inc. ("Mitek") moves for summary judgment that Arthrex, Inc. literally infringes claims 1, 2, 8, 9, and 12 of Mitek's U.S. Patent No. 5,314,446 ("446 Patent") by selling its FiberWire surgical suture.[1] Mitek's motion is predicated on the Court adopting Mitek's proposed constructions of the claim terms "PE" and "consistently essentially of."[2] If the Court adopts Mitek's construction for those two terms, then summary judgment of infringement should be granted because there are no genuine issues of material fact with respect to the structure of Arthrex's accused FiberWire products.

II. THE PARTIES AND THE SUTURE MARKETPLACE

Mitek is a company in Raynham, Massachusetts, and Defendants are Arthrex, a company in Naples, Florida and Pearsalls, Ltd., a UK company that manufactures the FiberWire suture for Arthrex. Mitek and Arthrex sell products, including sutures, used in orthopedic surgery. Sutures are a thread-like material that doctors and surgeons use for wound, tissue, tendon, or muscle repair. Sutures can be sold as "free strands" (*i.e.*, suture alone) or attached to a needle or anchor.[3] Pearsalls exclusively manufactures and imports FiberWire bulk suture into the United States for Arthrex. Pearsalls and Arthrex have worked together extensively as partners to design, develop, manufacture, and sell the accused FiberWire products.

---

[1] This memorandum is supported by "DePuy Mitek's Statement of Facts in Support of its Motion for Summary Judgment of Infringement and No Inequitable Conduct," and Exhibits attached thereto. Mitek's Statement of Material Facts is cited as "Mitek Fact #."

[2] Mitek, of course, does not concede non-infringement if the Court does not adopt its construction of the terms "PE" and "consisting essentially of." There will just likely be issues of fact that could preclude dispositive adjudication.

[3] Suture anchors are devices that implant into bone and are used in conjunction with a suture to reattach tendons, muscles, or ligaments to bone.

XI. CONCLUSION

Arthrex's and Pearsalls' inequitable conduct allegations are precisely the type of meritless allegations that the Federal Circuit has criticized as a "plague." No material information was withheld, and no material misrepresentations were made. The Examiner fully considered the references. Further, there is no evidence of intent to deceive. Summary judgment of Arthrex's inequitable conduct defenses and claims is warranted.

Dated: August 11, 2006

DEPUY MITEK, INC.,
By its attorneys,
_/s/ Erich M. Falke_____
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EXHIBIT 30

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

COPY

CIVIL ACTION
NO. 04-12457 PBS

DEPOSITION OF:	KEVIN GRIEFF
DATE:	September 15, 2005
TIME:	9:15 a.m. to 11:23 a.m.
LOCATION:	The Ritz Carlton Golf Resort 2600 Tiburon Drive Naples, FL 34112
TAKEN BY:	Plaintiff
REPORTER:	Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER:	Les Smoak, CLVS

A. I don't know how it would be different at Pearsalls, but, obviously, there would be a difference because it's a loop. I have no knowledge of how that's done.

Q. So is it your understanding that Pearsalls loops the FiberWire used to make the Arthrex FiberLoop product?

A. Pearsalls is the manufacturer of that. How they do it, I don't know.

Q. Now how does the manufacturing of Arthrex's FiberStick differ than -- strike that.

How does the manufacturing of Arthrex's FiberStick product differ than the manufacturing of Arthrex's FiberWire product?

A. It does not. It goes through the same processes with the same entities.

Q. Okay. Then how -- how is the FiberStick product different than the FiberWire product?

A. It has a longer tipping.

Q. And who does the tipping?

A. R.K. Manufacturing.

Q. And is the tipping just a longer portion of -- well, strike that.

What is the tipping process used for manufacturing Arthrex's FiberStick?

A. I'm not sure of the exact process, but tipping is

to make the suture rigid so you can pass it through instruments.

Q. Mmm-hmm.

A. The FiberStick just may have I believe 8 or 9 inches of tipping versus 1 inch of tipping.

Q. So other than the tipping for FiberStick, there's no other difference in the manufacturing process between FiberStick and FiberWire?

A. No, sir.

Q. How does the manufacturing of Arthrex's FiberSnare product differ than Arthrex's manufacturing of the FiberWire product?

MR. TAMBURO: Objection to form.

A. I'm not that familiar with the FiberSnare product, but I do not believe it's any different. It goes through -- it definitely goes through Pearsalls and R.K.

Q. Do you know what product number the FiberSnare is or what part number the FiberSnare?

A. 7209. AR-7209.

That's incorrect. That was the FiberStick. The FiberSnare, 7209SN.

Q. So AR-7209 SN is the FiberSnare product?

A. Correct.

Q. And that product, FiberSnare, is listed on Page ARM 18537 of Exhibit 101. And I believe that's Page 12-5

EXHIBIT 31

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446 AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

that while such braids will be highly pliable, they will also be relatively weak and unusable for most suture applications. Ex. 3 at col. 2, ll. 22-25.

The proposed solution described in the '446 patent is a heterogeneous braid made up of two dissimilar materials. According to the specification, the braid is made up of a first fiber-forming material mechanically interlocked or weaved with a second fiber-forming material. The specification also states that the first fiber-forming material is a lubricious material, and that the second fiber-forming material is added for strength. The fact that the first fiber-forming materials are lubricious but too weak for most suture applications is further made clear by the specification which states that "a volume fraction [of lubricating yarns] above about 80% may adversely affect the overall strength of the braid." As described throughout the specification, there is a tradeoff between the properties of the two materials – one being lubricious but weak, the other being added for strength. The specification further recognizes that gains in handleability/pliability outweigh any loss of strength.

The specification also repeatedly states that the advantage of the above-described braid construction is that the braid exhibits improved handleability and pliability without appreciably sacrificing its physical properties. Ex. 3 at col. 2, ll. 32 – 37; ll. 62 – 66; col. 6, ll. 7 – 8.

Claim 1 of the '446 patent is to a surgical suture, the surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous

C. UHMWPE is used in FiberWire to impart strength and PET is used in FiberWire to improve handleability

As I previously mentioned, the specification of the '446 patent describes that the first fiber-forming materials are added to improve suture handleability and that such materials are too weak for most suture applications. It is the second fiber-forming materials that are added for increased strength. The way in which the individual materials act in FiberWire is the opposite. UHMWPE that is added for strength and the PET is added to improve knot tying – a well-known handleability characteristic.

D. The basic and novel characteristics described in the '446 patent are a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties

I have been asked to provide my opinion regarding what a person of ordinary skill in the art in February 1992 would understand to be the basic and novel characteristics described in the '446 patent. It is my opinion that a person of ordinary skill in the art, in February 1992, reading the specification of the '446 patent would understand the basic and novel characteristics to be a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification. Ex. 3 at col. 2, ll. 32 – 37; ll. 62 – 66; col. 6, ll. 7 – 8.

The specification also describes that there is a tradeoff between the two fiber-forming materials that make up the two dissimilar yarns – one being lubricious, but

Based on my review of the three micrographs, it appears that they are very different and that they are too unclear to draw any conclusions from them. Despite the lack of clarity, however, it appears that the individual braid filaments are grouped together to a much greater degree in the Tab G micrograph than they are in the Tab E micrograph. This is an indication that coating has permeated into the braid.

In any event, Dr. Brookstein's conclusions are inconsistent with the findings discussed below. In addition to the tests described above, CETR also conducted a scanning electron microscopy (SEM) examination of coated and uncoated FiberWire suture. My review of the scans performed to date appears to indicate that the coating does extend into the braid. Ex. 20 at Fig. 14. This is consistent with the effect coating has on FiberWire's pliability, as described above.

F. The nylon added to TigerWire suture materially affects its pliability

I understand that Arthrex's TigerWire suture has the same construction as FiberWire suture except that one of the PET carriers is replaced with nylon 6,6. All the reasons discussed in connection with FiberWire also apply to TigerWire. Further, it is well known in the art of manufacturing and/or processing of fibers that nylon 6,6 fibers of the type used in TigerWire are generally more stiff (i.e., less pliable) than fibers made of PET, as used in FiberWire and TigerWire. Ex. 26. Therefore, the act of removing one PET carrier and replacing it with a nylon 6,6 carrier during the braiding process, as is done with TigerWire, introduces a less pliable material into the composite braid.

It is also my understanding from discussions with Bill Benavitz of Arthrex that the diameter of the nylon 6,6 fibers used in TigerWire is greater than that of the PET which it replaces. Therefore, the nylon 6,6 fiber makes up a greater percentage of the braid cross-section area than does the PET fiber it replaces. Mr. Benavitz also informed me that Arthrex has received customer feedback that TigerWire is more stiff than FiberWire. In addition, I held a sample of both commercial FiberWire and TigerWire and the TigerWire felt stiffer and more course than the same sized FiberWire. I also conducted the drape test on the two samples and found that the FiberWire conformed to the shape of my finger to a much greater degree than the TigerWire, indicating that the addition of the nylon appears to make TigerWire stiffer and less pliable. For these reasons, it is my opinion that the addition of nylon 6,6 in TigerWire materially affects its pliability. Moreover, the course feel would suggest that the addition of the nylon would adversely affect knot tie-down.

Dr. Brookstein stated that the purpose of the nylon included in TigerWire is for visual identification, and refers to Peter Dreyfuss's testimony to support his opinion. Brookstein Report at ¶ 46. Whether or not Dr. Brookstein's report is accurate, it does not change the fact that, as explained above, the addition of nylon materially affects TigerWire's pliability.

G. Adding an adhesive to FiberStick suture materially affects its handleability